INDEPENDENT REVIEW

Wales intensive care information system

SmartCo Consulting Ltd.

3rd September 2024

DOCUMENT INFORMATION

Title:	Wales Intensive Care Information System Independent Review
Version:	V1.0 Final
Date:	04/10/2024
Change Control	

Version	Date	Author(s)	Summary of Changes
0.1	22/07/2024	SmartCo	Initial Draft Outline
0.2	30/08/2024	SmartCo	Population post completion of Onsite Visits, Interviews and document Reviews
0.3	03/09/2024	SmartCo	Update following Data Triangulation
0.4	04/09/2024	SmartCo	Final updates & executive summary
0.5	04/09/2024	SmartCo	Internal Review updates
0.6	06/09/2024	SmartCo	Internal Review updates
0.7	25/09/2024	SmartCo	Updated to latest SCC report template
0.8	26/09/2024	SmartCo	NHS Wales, DHCW & CCIO comments incorporated for final Internal review
1.0	04/10/2024	SmartCo	Final for issue

Approvals

The following resources have reviewed and approved the content of this document:

Name	Title	Date Approved
[redacted]		

Table of Contents

Table of Figures

Table of Tables

1 Executive Summary

1.1 Background and Approach

An 'All Wales' digital programme was initiated in 2019 by the NHS Wales Collaborative on behalf of the Chief Executives and in response to a key priority request from the Critical Care Network. The Programme scope was to replace intensive care unit (ICU) paper records and streamline patient care through the implementation of the Wales Intensive Care Information System (WICIS). The contract was awarded to Ascom for their Digistat Solution. Digistat is a highly configurable Clinical IT toolkit, used in over 80 ICU's across Europe. The NHS Wales instance of Digistat (WICIS) was customised as part of the WICIS Programme to localise to Welsh requirements led by a team from Digital Health Care Wales across the programme life of 2019 to 2024.

The customised solution resulted in significant clinical safety concerns identified as a result of local user acceptance testing (UAT) at Aneurin Bevan University Health Board (ABUHB) in 2023. The clinical safety hazards & wider medico legal issues identified by ABUHB during UAT caused concerns to be raised across Health Boards in Wales, prompting a solution redesign proposal by Digital Heath and Care Wales (DHCW). Ahead of the proposal from DHCW to NHS Wales the ICU Clinical Leads Group met to agree support for a simplification proposal (16-Apr-2024), a costed proposal was submitted by DHCW to NHS Wales (25-Apr-2024).

Subsequently, conflicting letters were received from the CNIO community and the ICU Clinical Network. Given these differing clinical views and the concerns regarding the simplification proposal, SmartCo were commissioned to undertake an independent review of the programme.

The independent review was limited to specific objectives set by Welsh Government and involved various data collection methods, including desktop research, stakeholder interviews and a survey to ensure broader engagement, with an in person, onsite visit to ABUHB ICU to assess the specific clinical safety hazards escalated to DHCW. This review report provides key clinical safety observations and themes, and makes several recommendations in terms of next steps.

1.2 Review of Clinical Safety Assessments

Ensuring clinical safety in digital clinical systems is crucial throughout all stages of digital transformation programmes. Clinical safety reviews are required at procurement, as part of design decisions, prior to solution configuration, and throughout testing, leading up to go-live and adoption. The programme's clinical safety approach intended to adhere to NHS England's DCB standards, but evidence shows that clinical safety was treated in isolation and began late in the programme.

1.2.1 Ascom Safety Approach

SafeHand, a clinical safety consultancy, was commissioned by the supplier, Ascom, to oversee their clinical safety activities. Key functionalities such as electronic prescribing and medical devices were

initially placed out of scope. These appear to have not been flagged by DHCW's review but were later brought into scope following ABUHB's review.

The late commencement and release of the supplier's DCB0129 V1 is likely to have impacted the embedding of clinical safety into local design and configuration processes. Their DCB0129 is representative of a fair manufacturers' clinical safety case, but processes could be improved by closely reviewing the Health Board clinical safety case reports and hazard logs iteratively throughout the contract's lifespan.

1.2.2 DHCW Safety Approach

The safety case is both authored and approved by a DHCW Information Governance and Patient Safety Officer, with a placeholder for authorisation by the DHCW Associate Director of Patient Safety. The report does not include a safety plan, and the qualifications and relevant experience of the authors in running digital clinical safety workshops is not provided. The review found that the safety case document template was established in January 2023, but significant activity only began 6 months later, upon receipt of the supplier's DCB0129, after all major design decisions had completed.

The reviewer's opinion is that the process of Clinical Safety assessment is not apparent throughout the life of the WICIS programme. Bespoke developments and designs for Wales were not collaboratively assessed for safety implications ahead of development (i.e. a move to Context Launched results, instead of active data, design and development of static PDFs for patient Clinical overviews, exclusion and then late re-inclusion of Medicines Management for example and ePMA not being flagged by DHCW as being excluded from the suppliers DCB0129 despite inclusion in the ITT requirements.) The Hazard log does not detail who was involved in the hazard identification and analysis and the Clinical Safety Case report and Hazard log documentation appear to be a retrospective commenced towards the end of the project post receipt of the (late) suppliers DCB0129 Safety Case and a 'pseudo' Hazard review tagged onto as part of DHCW led System testing, rather than throughout the life of the programme. Requests to DHCW for copies of the Clinical Risk Management Plan (CRMP) for the WICIS solution were not responded to within review period. It was noted through interviews that several changes in DHCW Clinical Safety Officer happened through the life of the project the safety case hazards workshop was integrated into the DHCW two-day UAT, which is unlikely to have allowed for a comprehensive real-world system test or sufficient check and challenge by attendees whose original scope for attendance was to undertake system testing.

1.2.3 ABUHB Safety Approach

ABUHB conducted its own UAT commencing in October 2023. Clinical safety hazards pertaining to incomplete workflows, medication safety, and data visualisation issues were raised. Issues with the Digistat module were formally escalated by the Director of Pharmacy for not meeting safe prescribing and medicines administration standards. At time of ceasing testing in January 2024, 269 entries on the ABUHB issues log had been identified and shared for DHCW review and

engagement. At the time of SmartCo's onsite review in August 2024 ABUHB reported they had yet to receive comments or any engagement on the issues they had identified.

1.3 Onsite ABUHB Review

As part of the independent review, an onsite review of the WICIS solution led by the ABUHB team, alongside their documented hazards was undertaken at the end of August 2024. The visit reviewed key functionality across the workings of a multidisciplinary team, within the environment of an ICU bay, with connected medical devices, and the typical working environment of the ABUHB ICU team.

Specific functionality and workflows assessed included:

- Handover, recording of vital signs
- Medicines management
- Laboratory results
- Nursing care plans
- Data recording, visualisation and information sharing

The review found the current design of the WICIS solution to have a fragmented structure, resulting in increased documentation burden and inefficiency. The lack of a summary page and the use of PDFs for presenting time static information were identified as ineffective. It is clear a redesign is required, combining structured and unstructured data capture, allowing clinical professional narrative with a more effective design for the necessary processes, which require often fast paced and dynamic combined data review, analysis and articulation of life changing clinical assessments and plans within the ICU.

1.4 Other Contributing Factors

Throughout the independent review the following factors which can impact effective clinical safety processes were considered, with an overarching recommendation for a full lessons learned review being commissioned to assist a programme reset and successful outcome to the digitalisation of ICU across Wales.

- Governance and reporting
- Organisational, operational and technical readiness
- Stakeholder management, communications and engagement
- Solution Design Authorities and change control

1.5 Conclusions

Following the assessment of the current WICIS solution delivered to ABUHB, our conclusion is that the solution is not safe to go live due to the many identified issues. Insufficient continuous engagement throughout the procurement, design and configuration phases upto 2023 led to a

loss of confidence among frontline clinicians and executives. Moreover, the technology, designed to deliver a single solution for all ICU care activities, was found to be cumbersome, posing risks around prescribing, data documentation and retrieval. Collaborative efforts are needed to address these challenges before considering going live.

The proposal to simplify the Digistat module was reviewed and it was found that further consultation would be needed between Health Boards, DHCW and the supplier to specify a reshaped design, addressing hazards and mitigating these to a level that is as low as reasonably possible, with a holistic approach addressing the highly interrelated, multidisciplinary team nature of the ICU environment.

There is appetite from all stakeholders to digitalise their ICUs. If such a programme is to succeed, a reset will be required, reshaping not only the solution to meet user needs but the programme governance, controls and particularly the approach to include and fully engage end users throughout design, development, deployment and adoption. Close engagement between parties and a willingness to collaborate to reshape the solution and programme approach could yet lead to a future successful deployment.

Lastly, considering the changing digital health landscape, NHS Wales is recommended to review its wider strategic plans with a blueprint for achieving a fully digital health system.

The review concludes that this is a programme failure, ***not necessarily*** a product failure.

1.6 Summary of Recommendations

No.	Recommendations
1	The current configuration of the WICIS solution is not safe to take live.
2	The current 'simplification' proposal requires further detailed design review with stakeholders across DHCW, Health Boards and Ascom, including an iterative design approach with clinical safety hazard assessment at its core.
3	The reshaping of the solution, to better and safely meet local clinical process needs, is not simple and requires a resetting of the programme governance and engagement approach alongside the solution design.
4	The hazards identified through ABUHB's UAT should be collaboratively reviewed, ideally with an independent clinical safety facilitator, with the outputs taken into consideration for any solution redesign.
5	A full lessons learned review should be commissioned to enable the wider learning to support reshaping of the WICIS programme and other All Wales digital transformation programmes
6	Any Programme reset and full lessons learned should consider the Governance needs of a collaborative multidisciplinary approach to assurance and clear engagement, responsibilities and accountability for all involved organisations (Strategic Health Authorities, Health Boards & Suppliers & wider).
7	The changed digital landscape and strategic context since 2019 should be considered with any reset of the programme.
8	An Interactive approach to using Discrete Diagnostic Results must be achieved for safe, useable Clinical IT Systems such as ICU's/ePMA's and wider.
9	NHS Wales should look to mandate a policy for clinical safety akin to the DCB0129 and 0160 standards, establishing a network of trained and qualified clinical safety professionals across DHCW and Health Boards.

Table 1: Report recommendations

2 Introduction

2.1 Background & Context

In 2019, in response to a request from the Welsh Critical Care Network, the NHS Wales Health Collaborative and DHCW established a programme to deliver an all-Wales digital solution that would fully support patient care and enable flow of patient information across all adult critical care services in Wales.

This was an ambitious and complex programme replacing all paper records and other critical care clinical information systems ensuring that the full patient record could be managed in one place and viewed by clinical staff across all seven health boards.

Ascom was selected as the supplier, and DHCW was tasked by NHS Wales with designing, deploying, and managing the programme across all Welsh Health Boards, including supplier relationship and contract management. The project aimed to be a long-term partnership, involving joint development of the Ascom Digistat solution for all 14 hospitals in Wales, potentially covering up to 240 beds.

The project was anticipated to last seven years, with deployment across all 14 hospitals within three years. It focused on digitalising the entire ICU process using Digistat, an ICU patient data management solution widely used in Europe.

The NHS Collaborative & ICU Network Clinical Lead led the development of requirements, design, and configuration decisions for the Ascom solution, supported by two lead clinical roles (a practicing ICU consultant as lead ICU CCIO employed by NHS Exec and a nurse employed by DHCW) along with other clinicians and digital health professionals funded centrally from across DHCW and Health Boards. Localised design elicitation for the Welsh implementation were made through workshops involving stakeholders from all Health Boards and critical care disciplines. It is key to note that through the programme there were several changes in governance the full chronology of which is not recorded by this report, however key changes include.

- Change of ICU CCIO in 2023.
- Change from NHS Wales Collaborative to NHS Exec
- Change of Programme SRO Organisation between NHS Exec to DHCW
- DHCW SRO Delegation to Director of Programmes & Engagement.

Ascom provided an initial Clinical Safety Case (DCB0129) in June 2023, which was revised to version 1.1 in October 2023, adhering to NHS England's DCB0129 Clinical Risk Management standards. DHCW produced a Clinical Safety Case (DCB0160) and a hazard log (November 2023), authored by DHCW based on a national UAT approach. The DHCW clinical hazard review identified 34 hazards, with four classified as significant and exceeding the recommended risk levels for solution deployment. Despite these significant hazards, the solution was considered safer than current paper processes and was authorised for use.

In addition to central UAT, local UAT at ABUHB took place towards the end of 2023 and early 2024. Local UAT was not factored into the Programme Plans, however our review identified this was supported by Health Boards and specifically requested by NHS Wales as part of assurance processes.

The ABUHB UAT commenced in October 2023 resulted in a log of 269 clinical hazards and other issues, including medico-legal concerns, which were shared with DHCW. The evaluation led ABUHB executives to inform DHCW that they could not accept the product as designed due to safety concerns.

The substantial number of hazards raised by ABUHB, being the first Health Board to locally test and assess the solution, caused widespread concern among Health Boards in Wales. There are varying degrees of concern regarding the clinical safety of the product.

DHCW undertook a review of the ABUHB hazard log, in comparison with supplier and DHCW's safety reviews, this led to a proposed redesign of the solution (termed 'simplification') to improve workflow efficiency and address the safety concerns raised.

After review by the ICU Networks Clinical leads (16-Apr-2024), DHCW presented NHS Wales with three options in an escalation report (WICIS Escalation Paper, April 25, 2024):

1) Additional funding and Health Board commitment
2) Reprofile implementation costs
3) Contract termination

All three options necessitate further time and funding.

NHS Wales had concerns about the robustness of the redesign simplification proposal, its costings and whether the eventual solution would be fit for purpose within intensive care settings and ultimately be accepted by Health Boards.

Furthermore, there were different clinical voices speaking to the issue. The Chief Nurse Information Officers from the Health Boards sent a letter of concern stating

> "nurses are reluctant to support continuing with the development of the current system, as the proposals as they stood mean the system will continue to not be fit for purpose for nursing." - WICISNursing Letter 2024 03 30

The Critical Care Network sent a further letter that offered unequivocal support to continue the project with the caveat:

> "the scope of the system would need to be simplified further." … "Without continuation of the project, it is likely that there be significant delays in reaping the benefits of a unified informatics system, for example: delivering care closer to home under remote support from tertiary units and seamless movement of patients between secondary and tertiary critical care units in Wales." - Critical Care Network 18 July 2024

In response to this complexity and the diversity of opinions, Welsh Government commissioned SmartCo to conduct an independent review of the WICIS solution. Welsh Government and NHS Wales set the following objectives for the review:

- Provide an assessment on the adequacy of the clinical safety work undertaken
- Assess the proposed simplification approach and whether the proposed work could result in a usable and clinically safe solution

This report presents the key findings of the review:

- Section 1 outlines the methods used
- Section 2 details findings
- Section 3 discusses findings and provides recommendations

3 Section 1: Methodology

The following section provides a summary of the approach used to conduct this independent review.

3.1 Overview

The review was conducted over a compressed three-week period. The team consisted of an experienced Clinical Nurse Informatics Officer (CNIO) with a clinical background in intensive care nursing and a Chief Informatics Officer (CIO) with extensive experience in the procurement and delivery of digital health solutions including those designed for intensive care. They were supported by a core delivery team from SmartCo Consulting. Profiles are provided in Appendix D.

3.1.1 Aim

The aim of this review was to:

- Provide an assessment on the adequacy of the clinical safety work undertaken
- Assess the proposed simplification approach and whether it could result in a usable and clinically safe solution

3.1.2 Scope

The scope of the review was limited to addressing the objectives laid down by NHS Wales:

- The adequacy of the clinical safety work undertaken
- Review the existing WICIS Review Recommendations for the proposal to redevelop the solution
- Provide an expert opinion on the suitability of the WICIS review recommendations report including the proposed approach
- Safety should consider both the usability as well as inherent and residual clinical risk(s)

3.1.3 Data Collection

Multiple methods were used for this review, these included desktop research of documents, administration of a questionnaire, stakeholder interviews, demonstrations of the WICIS solution and an on-site visit to ABUHB for a demonstration where several core workflows were assessed against the hazards and issues log provided. Figure 1 provides an overview of the types and volume of data gathered to inform this review. Data sources are referenced throughout the document. Figure 2 provides an overview of the number and range of interviews conducted.

For further details on the data gathered and reviewed refer to the appendices:

- Appendix A provides details of interviews conducted
- Appendix B details each document collected and tracked
- Appendix C shows the survey questions & analysis of results and the agenda of the onsite visits

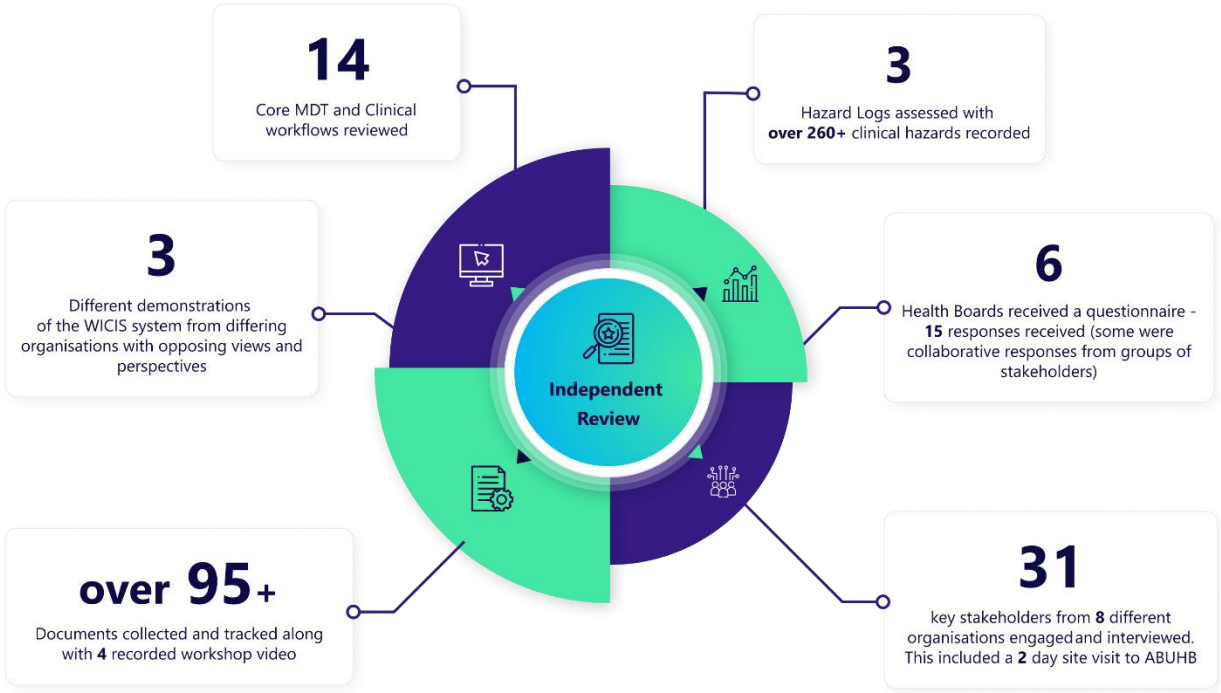


Figure 1: Volume of data collected

Figure 2: Breakdown of stakeholders engaged by organisation

3.1.4 Data Analysis

Data was reviewed iteratively throughout the review and these generated lines of enquiry where further data was sought. Rich description has been used to represent findings on the use of WICIS in clinical practice and to represent the safety activities of all organisations involved. A process of data triangulation has been used to inform the conclusion and recommendations within this report.

It is impossible to address the aims of this review without some consideration of context and consequently, additional themes have been identified and are examined in Section 6 - Contributory factors/key observations. The aims are shown in 3.1.1.

3.1.5 Limitations

Authors undertaking the review and report would like to note the following limitations:

1) The timebound nature of the review meant that stakeholder interviews were limited to focus on key personnel in DHCW, Ascom and the two Health Boards identified by DHCW as early adopters (ABUHB & SBUHB). In addition, interviews were conducted with [redacted], letters of support and concern from multidisciplinary clinicians were considered. In addition, a survey was undertaken to provide stakeholders across all health boards an opportunity to contribute. Further engagement with [redacted] were included as part of clarifications prior to writing this report
2) Detailed review of procurement supplier responses and demonstrations is out of scope of the review
3) The redesign of the solution, the rewrite of the Clinical Safety Case, and a detailed lessons-learned review are outside the scope of this review as set by NHS Wales. However, key clinical safety observations and themes from the documents and interviews are provided to inform any future review and potential programme reset
4) Given the programme's complexity and duration, further work to gather lessons learned and guide future actions is significant but beyond the scope of this commissioned work

The results should be interpreted accordingly, and the recommendations will highlight additional necessary activities.

4 Section 2: Safety Findings

The process of ensuring clinical safety in digital solutions spans all stages of managing a project or programme, from startup and initiation to controlling stages, managing stage boundaries, and closing the project. Key safety reviews should be conducted during design decisions, prior to solution configuration, and throughout testing, leading up to the eventual go-live and adoption. A safety review structure must also be in place to respond to issues and maintain safety processes throughout the asset's lifecycle, including its eventual decommissioning. Evidence reviewed indicates that safety was treated in isolation and began late in this programme.

A Clinical Safety Case written to NHS England's DCB standards consist of three main components:

- A Safety Plan - detailing how the safety of solution will be managed through initiation and development, continued use and eventual decommission
- A Hazard Log - detailing the analysis, classification, assessment and any control measures to reduce likelihood or impact to 'As Low as Reasonably Possible' (ALARP)
- A Safety Case Report - which details the process the scope, the outcomes of testing and who was involved, including the appointed Clinical Safety Officers (CSO) statement[1]

The Clinical Safety approach for this programme was intended to follow these standards. The following sections will address each organisations safety assessments in turn.

4.1 Ascom Safety Activities

Ascom commissioned an DCB0129 at the request of NHS Wales, outsourcing its safety activities to SafeHand, a specialist clinical safety consultancy. This was commenced very late in the project, the initial report dated 2nd June 2023 indicates design decisions where bespoke developments for Wales were not considered at design stage, only upon completion in readiness for central DHCW UAT.

SafeHand are a highly regarded specialist Clinical Safety Consultancy, widely used by suppliers and sometimes the NHS.

Our review of the case was limited to Hazard log and Clinical Safety Case report, it did not review the Safety plan as this was not made available at the time of writing. The review has indicated that the V1 of the DCB0129 was written and authorised by the same individual. From interviews with Ascom and SafeHand, it became apparent that some wider engagement was undertaken by the Ascom Clinical Lead to assist reviews of functionality and identified hazards. These were further

[1] It is worth noting that although these standards were written for England and Wales, they are not yet mandated for use in Wales. It is understood that Wales is in the process of developing its own version.

supported by Ascom's Technical Solution lead. However, a limitation would have been that the hazard review workshops would not have included SME's or practicing physicians, nurses or Allied Health Professionals (AHPs) from Wales. Although not typical with mature and widely adopted systems, when developing a solution to a single customer's specific requirements or a first of type for a country, involving the end user SME experience and knowledge as part of the supplier hazard workshops can improve outcomes. This is particularly relevant when bespoke developments are designed, enabling collaborative hazard analysis drawing upon knowledge of the physical environment in which the solution will be used.

Interviews with Ascom and their specialist Clinical Safety advisors [redacted], expressed that the method for hazard identification and analysis was undertaken using a SWIFT (So What If This) approach. Other methods may return wider hazards for consideration or identify greater input and output controls. Specifically combining a SWIFT analysis with a Bowtie Risk method to identify pre-hazard controls to reduce the likelihood of an event occurring, and post event controls to reduce the impact.

Version 1.0 was shared to reviewers by DHCW indicating this version was used for the DHCW DCB0160. It is apparent when comparing this to the ITT requirements, that the DCB0129 v1.0 places key and critical functionality such as electronic prescribing and medicines administration (therapies) as out of scope, along with medical devices and other key modules.

Although out of scope in the Clinical Safety Case report the DCB0129 Hazard log predominantly pertains to medicines management, which could call into question the accuracy of Ascom's DCB0129 v1 Clinical Safety Case report. On check and challenge with Ascom and reviewing dates a version v1.01 was shared direct from the supplier. Upon review, it would be fair to assume that the Hazard log shared with the inaugural v1 CSCR had commenced assessment of the medicines management (and other functionalities deemed out of scope in v1) ahead of the Clinical Safety Case report v1.01 being finalised.

Through interviews with Ascom, it became apparent that these excluded modules which DHCW had not confirmed as in scope for the initial release but were then later confirmed, brought into scope and subsequently included in a version 1.01 (3rd Oct 2023) and v1.1 (11th Oct 2023). The Ascom timeline supports this. Ascom advise both subsequent versions of the Safety Case reports and Hazard logs were shared to DHCW upon approval in October 2023.

The sharing of the wrong CSCR to reviewers by DHCW would point to possible wider Project Library and version control issues, but this has not been checked due to time limitations and may be an area for any future lessons learned review.

As such, the latest version of DCB0129 v.1.1 is stated as the latest version by Ascom and SafeHand.

Through interviews with DHCW and Health Boards there appears to be a view that the Ascom DCB0129 is very generic and not specific to the WICIS solution. Upon review, the authors of this report can advise the DCB0129's Clinical Safety Case report is specifically WICIS focussed and not relating to other country/versions of the Digitstat product. However, the Hazard log, does appear

to have generic hazards, this may be down to the wide configurability of the solution requiring customers to be diligent in their configuration and design decisions. The hazards identified by ABUHB regarding the complexity of using of multiple modules simultaneously, without the active clinical assessments remaining open have not been identified, analysed and assessed by the DHCW or Ascom safety reports. Furthermore, it is likely that the late release of DCB0129 V1 will not have aided a full and proper DCB0160 safety process embedded into local design & configuration processes.

Further interviews with Health Boards questioned the Customer / Supplier nature of Ascom and DHCW, with both defined within the Programme Board ToR as suppliers to Health Boards, particular questions arose pertaining to responsibilities in discharging duties on the Clinical Safety Case and Medical Devices Regulations (MDR). Namely, who is the registered UK Responsible Person (UKRP) for distribution of the Ascom Digistat solution, Ascom or DHCW? Through clarifications and certificate review, it is possible to ascertain that the registered UKRP is Ascom, and Ascom have confirmed this responsibility. These RACI intricacies are not covered within either the Ascom DCB019 or DHCW's DCB0160.

Other points to note regarding suppliers DCB0129:

- Supplier identified hazards do not consider interface failures, and there are a number of systems being interfaced with such as PAS / MPI / Labs / Doc Mgt / Clin Portal / medical devices
- The CSCR feels bespoke to WICIS, which is good. But the Hazard log would appear to be a generic list of preexisting typical hazards and controls
- The DCB0129 Safety Case does not clearly identify which hazards are being handed to the Customer to manage through local controls

The DCB0129 is a fair representation of a manufacturers Clinical Safety Case, supported by the MHRA Class II documentation. It would, however, be improved on by closely considering and reviewing the eventual Health Board Clinical Safety Case reports, and Hazard logs in an iterative method throughout the lifecycle of the contract. Any lessons learned review should consider the manufacturers Clinical Safety Plan documentation to ensure this feedback loop is included.

Recommendation: For consideration with any reset and lessons learned - roles and responsibilities for Safety Cases and MHRA duties, should be clearly defined upfront. It would be reasonable and practical for the Health Boards and DHCW to compile a collaborative DCB0160 Safety Case and collective Hazard log, with robust representation when analysing hazards. A central core DCB0160 could be published by DHCW with Individual Health Boards providing a localised Appendix of local issues. These Appendixes would be focussed on unique and localised issues pertaining to that Health Boards implementation, such as any infrastructure, training, constraints or specialised workflows (i.e. Tertiary Neuro Centres specific receiving and discharging workflows pertaining to referrals and discharges). Additionally, any variations in surrounding technologies such as Ward and Pharmacy based processes, Theatres and Anaesthetics. This would ensure wide reach, engagement and inclusion in the Safety Case and its hazards analysis.

4.2 DHCW Safety Approach

The suppliers DCB0129 is used to initiate and inform the customers Clinical Safety Case (Plan, Hazards and Report) as some hazards and controls may be passed to the customer to mitigate through design decisions, configuration and / or End User Training and awareness. The local configuration, bespoke developments, design decisions such as choosing to use a system in a way the manufacturer had not intended can have material implications on the future liability should something go wrong and found to have not been appropriately assessed.

The DHCW safety case is authored and approved by a [redacted], with a placeholder for authorisation by [redacted]. The version shared for review does not contain the authorisation signature or date of authorisation by the [redacted]. This may be an administrative process, with the report signed off through the recorded minutes and these not shared. Any lessons learned review should check process for final authorisation and recording sign off's/approvals within the report itself as documents that are utilised over the lifecycle of solutions and sometimes out living the contract itself.

The DHCW DCB0160 does not include a Safety Plan, this has been requested but not received at time of report writing. The Safety plan would be useful in assessing when safety activities were planned, the overarching governance and robustness of hazard analysis including whether design decisions were assessed prior to confirmation for build into the solution, along with opportunities for the Programmes Governances structure to check & challenge. The plan would also set out clear roles and responsibilities of how any incident response of hazards (should they arise in live use of the solution) would be managed and co-ordinated.

It is not clear from the DHCW Safety Case report the qualifications of the authors, whether they have been formerly trained in the DCB0160 standard or how experienced the authors are in running Digital Clinical Safety workshops and analysis. A separate lessons' learned review may wish to investigate this, for the purpose of improving processes and awareness. It is common practice to include the Authors and Reviewers credentials and relevance to any hazard analysis, along with a table of who was involved in each hazard review.

The process of Safety Case creation and hazard identification and analysis can be best understood from a subsection of the overall timeline, this shows that:

Timeline	Activity
Jan-2023	DHCW DCB0160 Template Created & Ascom Safety Case Requested
02-Jun-2023	Ascom DCB0129 v1 released
24-Jul-2023	DHCW Hazard Workshop Equivalence through End-to-End Testing
17-Aug-2023	WICIS UAT Summary Report (FINAL APPRIVED)
14-Oct-2023	DHCW Hazards reviewed and updated
17-Nov-2023	DHCW Hazards reviewed and updated

17-Nov-2023	DHCW DCB0160 V1 Presented to Patient Safety Board noting Initial Assessment said unsafe however on review 'Top Management' deemed safe to deploy as no greater risk than paper

Table 2: Safety Case timeline

Subsequent clarification has been offered by DHCW which advises wider workshops happened, however no evidence of Clinical Risk Management Plan or details of the workshops and attendee's has been provided.

From the above timeline and combining with other project timelines shared, it is possible to determine that although the DHCW Safety Case template was setup in January 2023, main activity commenced upon receipt of the supplier DCB0129, which was two years post elicitation of requirements workshops. This is too late in a programme for Safety processes to commence.

A Safety Case Hazards workshop equivalence was managed through the DHCW two days End User Testing. However, through interviews it was noted that although the DHCW workshops were attended by members of the Health Boards, test scripts were prescriptive and may not have allowed for a holistic 'real world' system test and therefore hazard identification may not have been robust. Two days alongside the intended testing is not a significant amount of focussed time and the roles/responsibilities of those attending the planned testing workshops pertaining to combined Safety Case and hazard analysis may not have been clear to attendees. It is good practice to take testing into account, however attendees should be aware of the need to identify and record any clinical hazards alongside defects identified at testing with subsequent workshops to analyse the hazards running a drill down into cause, effect and controls.

A subsequent lesson learned review may wish to review the processes in more detail with the following questions in mind:

- Are Clinical Safety processes started early enough in a programme to effect outcome?
- Are all resources involved at each stage aware of Clinical Safety processes and practices
- Are all adequately trained or informed of their roles and responsibilities
- Is appropriate governance in place with appropriate assurances
- Is 'Top Management' reviews and analysis adequately documented and appropriately challenged
- Are End Users adequately engaged through hazard identification, design decisions
- Are End Users provided with a Clinical Safety process overview prior to being enlisted?
- Does testing adequately reflect 'real world' use (environment, human factors, competing priorities., as well as timelines between activities)?
- Is a matrix detailing who was involved in each hazard being reviewed and their appropriateness for inclusion in review?
- Has the Board that ultimately signs off been kept informed and involved throughout the lifecycle, or simply presented a report at the end of a process?

4.3 Aneurin Bevan Safety Approach

In October 2023 the product was handed over to ABUHB who proceeded to undertake End User Training and further UAT. Serious concerns were raised through this activity and the onsite training, these were captured in a Hazard log completed by the [redacted] with extensive experience in patient safety. These are captured in a spreadsheet which is more than a Hazard log and is subdivided into the following sections:

- Clinical Hazards: where the use of the solution creates a clinical hazard n=92
- Therapies: clinical hazards associated with medicines prescribing and administration n=84
- Medicolegal: where the design presents issues associated with record keeping for medicolegal purposes n=50

The hazard rating system utilised by ABUHB differs to the NHS England DCB160 process and that used by Ascom and DHCW. The ABUHB method utilises a commonly used 5 x 5 probability/impact risk management method resulting in scores ranging from 1 to 25. Whereas the Ascom & DHCW Hazard log utilises the NHS England Safety Classification matrix, which also uses a 5 x 5 matrix, but groups scores to maximum level of 1 to 4. It is possible to map the two methodologies to enable consistency, however the methodology for assigning probability have differing methods and meanings. The ABUHB log identifies 11 x 25 scored hazards, 8 of which pertaining to Medicolegal hazards and 3 pertaining to prescribing or clinical functionalities. With a further 37 attaining a score of 20.

Recommendation: With analysis of ABUHB Hazard log, remapping to a common scoring method should be undertaken ensuring consistent use of 'Likelihood' and 'Impact'.

Recommendation: ABUHB Hazard log to be reviewed with ASCOM, DHCW, ABUHB and other willing Health Board WICIS leads alongside the DHCW 'Simplification' proposal and high-level 'DHCW/Ascom Excel analysis' to form the basis of a solution re-development proposal. A combined DHCW/Health Boards Safety Case process should be undertaken throughout this review.

4.3.1 Clinical Hazards

84 of the 221 clinical hazards identified relate to medicines administration and prescription. Repeatedly, those interviewed and project documents, state the Digistat Therapies module is not an ePMA. However, the module is used for prescribing and administration of medications. Thus, it constitutes part of the patient record and is the digital legal document for this activity. It is likely some confusion has been introduced by the Ascom solution reportedly not having Clinical Decision Support System (CDSS) rules pertaining to Medicines Prescribing and Administration. This confusion and interpretation that WICIS is not an ePMA is likely to have been fundamental to decisions taken by DHCW.

> After mitigation and hazard evaluation 4 hazards remained with a significant risk rating of 8. Two of these hazards WICIS 26 & 30 were attributed to the system not having clinical decision support to aid the administration and prescription of the therapies module. This functionality was out of scope for the WICIS project and the use case for the therapy's module was to enable clinicians to have a record of medications digitally and replace the paper process in line with the main aim of the project. (DHCW Clinical Safety Case Report 17 Nov 2023)

The DHCW Safety Case asserts that the Therapies module has similar risks to paper charts. However, paper charts are structured with key information to support clinical decision making and they are structured to support easy visualisation of key information by using groupings and colour coding. Therefore, the reviewers conclude that based on an assessment of the documentary evidence and a demonstration of the medicines module the current solution is not safer than paper. Furthermore, there remain significant amounts of development to do to achieve a solution that makes the most of digital technologies and user centred design to support the safe prescribing and administration of medicines. The [redacted] undertook significant engagement and redesign of the therapies module to make it safer. Introducing order sets built by two pharmacists seconded to the project to review the thousands of drugs in the formulary, dose omission rules. However, the module still lacks CDSS functionality and should ideally have a Drug Multilex such as First Databanks Drug/Drug drug/food and drug/allergy checking. These were not stated as requirements in the tender requirements. Our review checked and challenged this capability with Ascom and Ascom confirmed similar drug multilex's were used in other countries. However, they had not encountered or integrated First Databank solution as commonly used in the UK.

64 of the clinical hazards relate to data visualisation through the bespoke customisation of Digistat for WICIS e.g. using PDFs to view historical information in relation to the task at hand. These static reports have each been individually configured and were hard to navigate as they had so much information within them, much of which was not in fact relevant. The structure of the digital record should support easy navigation to enable retrospective analysis to support clinical decision making and care.

4.3.2 Medicolegal Issues

48 issues in the ABUHB Hazard log includes a section on medicolegal issues, which, while not required for safety cases, are important and need to be fully understood and addressed through technical, process or training mitigation measures. It is important to note that many of these medicolegal issues also appear as clinical hazards on the ABUHB spreadsheet and so there is an element of double counting with the same issue presented through two different lenses.

One of the highest scoring medicolegal concerns is the solution's treatment of health record entries as drafts that must be validated before being saved. During the visit to ABUHB, this workflow was demonstrated. Reviewers observed that a clinician cannot leave a previous clinician's document in draft and start a new record until the draft is validated and saved. This creates a

dilemma; the clinician must choose between creating a safety risk by delaying care or accepting the medicolegal risk of being the accountable author of an entry, that is not theirs and could be inaccurate, to proceed with care.

Ascom confirmed that the 'Drafts' functionality was a bespoke development for WICIS, and its final implementation may have deviated from the original intent.

Professional responsibilities, laid down by the regulatory bodies, for documenting assessments and care are the same for both paper and digital records. While the draft function may have been developed as a technical solution that allows clinicians in fast-paced environments like ICU to pause and complete records later, it appears that policy and process as mitigation methods were not explored. This is one of many examples where the lack of closed loop consistent engagement with subject matter experts (SME's) throughout the programme led to the large volume of risks and issues that were highlighted late in the programme through the ABUHB hazard log and evaluation report.

4.4 Safety Comparisons

To assess the true level of risk an assessment by DHCW of the different hazard logs was undertaken and a report generated. There are some limitations of this report the most significant being that it was done in isolation. ABUHB advise they are awaiting the opportunity to engage with the suppliers, Ascom and DHCW, to work through the issues raised. To truly assess the level of risk from ABUHB's UAT and safety activities an independently facilitated collaborative approach with all the relevant SME's needs to be conducted. This will provide an opportunity to assess the risks, score them, identify mitigations that are acceptable to all and reassess the overall risk before moving forward. This should happen as a priority.

4.5 Reviewers Comparisons

There are several issues in comparing the safety approach and activities of all organisations. These are:

1) Lack of hazard identification through design processes
2) Use of different categorisations
3) Use of different scoring methods, which should not be simply grouped by a calculated output score, but the methodology for assessment and categorisation of 'Likelihood' and 'Impact' aligned and the input and output controls collaboratively assessed to enable an agreed mitigated hazard score

In conclusion, it is the volume and combination of issues that have surfaced through the UAT and safety activities at ABUHB that lead us to conclude that the solution is not safe to go live as it is currently configured. The volume of issues and extensive change in current practice required means that the level of training and education needed to practice safely, coupled with the lack of local champions who have knowledge of and confidence in the solution, means that any attempt

to go live would result in failure to adopt and certainly lead to an increase in patient safety incidents.

5 ABUHB Site Visit: Assessment Of Functionality & Product Useability

5.1 Overview

There is extensive evidence to show that electronic records must be designed with a focus on workflow integration, usability interface and design if they are to be used effectively to deliver benefits in patient safety and productivity (Gardner 2018, Ratwani 2019, Sinsky et al 2016). A study published in the *Journal of the American Medical Informatics Association* (Russ et al 2013) found that high cognitive load associated with complex EPR interfaces increases the likelihood of errors in data entry and decision-making. The study noted that simplifying user interfaces and reducing unnecessary steps can significantly decrease cognitive load and improve accuracy. Stevenson et al (2010) found that poorly designed EPR systems can create silos, leading to miscommunication and delays in patient care.

A key step in moving from a mixed economy of paper and digital records to deliver the ambition for an 'All Wales' comprehensive digital solution for intensive care would be to achieve some level of standardisation of practice. It was reported that this was achieved by sending in all paper documents to the central project team at DHCW. This team interpreted these to build the single solution. This approach has underestimated the complexity of the task of achieving standardisation through ongoing discourse with a large group of end users who are ready to practice in new ways.

In attempts to understand the usability and safety of the WICIS product the reviewers examined the evidence gathered through the lens of key workflows in the ICU. The onsite visit to ABUHB was structured to enable demonstration of these within the environment that the solution would be used. The following section describes key workflows and the strengths and limitation of the technology in supporting them.

5.2 Assessment and Documentation of Care Needs in ICU

The primary focus of all clinical staff in the ICU is on supporting the function of body systems in the acutely unwell patient. Consequently, a **systems-based model** is utilised, with **A-E (Airway, Breathing, Circulation, Disability, Exposure) assessments** supporting the evaluation of all body systems. A systems approach to documentation is used by all to facilitate effective MDT working, the process maps produced by ABUHB reflect this model of care.

Currently, **WICIS** does not provide a structured A-E assessment framework. The structure of these assessments in WICIS has been fragmented into multiple modules, resulting in numerous clicks in and out of different parts of the solution and necessitates multiple saves that if forgotten will lead to lost data. This unintuitive workflow increases the **documentation burden** and complicates obtaining a comprehensive view of the patient's overall care needs and ultimately creates risk. A check and challenge of the time and motion study provided by ABUHB demonstrated that for a

nurse to admit a new intubated patient to the ICU would require navigating across 12 different modules resulting in over 300 mouse clicks. Whilst undoubtedly, they would get faster doing this over time, they are not likely to realise the benefit of a reduced documentation burden.

The modular assessment was a specific Wales design decision for WICIS, Ascom typically provides the more commonly used A-E structure for medical and nursing documentation. One AHBH usability Survey respondent commented.

> **Poor structure**: no logical flow (A-E), assessment info, scoring, and care bundles not together – time wasting and likelihood of info being missed, duplication of recording – time wasting and dangerous (NCP and other areas) with info able to be recorded in different places which don't talk (different versions of the truth), potential to miss mandatory information. (Response comment from ABUHB Usability Survey)"

5.3 Data Visualisation

The WICIS solution lacks a summary page that provides an at-a-glance view of the patient, with most of the patient landing page occupied by buttons for forms and modules. This modular approach to assessments makes it difficult to get a comprehensive view of the patient. Attempts to create this overview have involved embedding PDFs, a bespoke solution for WICIS.

The modular approach to assessments designed for WICIS makes it difficult to get a comprehensive view of the patient. Some attempts to coalesce information to provide this view has been attempted with embedded PDF's (figure 3), a bespoke solution designed for WICIS. This is a highly unusual way to achieve overview with numerous short fallings which increase clinical hazards, particularly providing a static view of data. With intuitive user centred design, it is possible to achieve this either through navigating the care record through a structured build with a limited number of tabs or utilising the Ascom Split screen functionality with access to live data modules.

Mock-up of Typical WICIS Split Screen with PDF Example

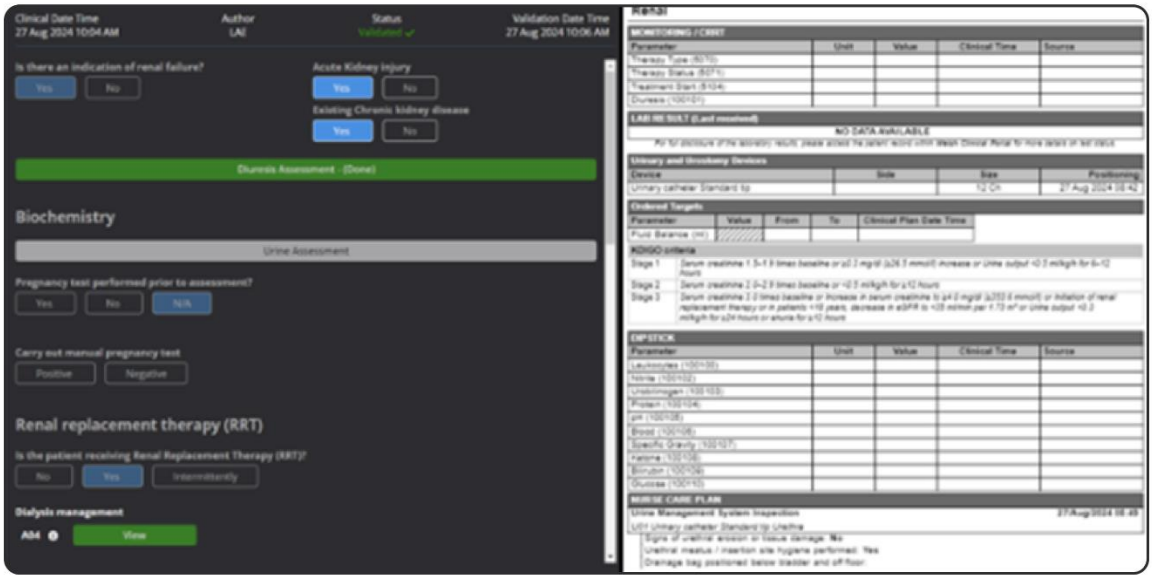


Figure 3: Mock-up of Split screen Assessment and PDF Clinical history view

Upon review, it is clear that alternative split screen views showing live data is achievable and implemented elsewhere through the Ascom Digitstat solution. The Ascom tender response also provides a visual overview of what has been achieved elsewhere. Ascoms ITT response is provided below.

> **"Fully Compliant. "**
>
> "We have incorporated a multi-screen modality within the software to enable users to view two parts of the record at the same time, helping to consume data from one area of the record whilst entering data to another ensuring that notes and decisions are based on the correct assessments. The multi-screen view can work as a split screen on a single monitor or activate multiple monitors on one PC if the hardware is available. Either way the functionality remains the same in that, as an example, the clinical diary can be open for note entries whilst the online module presenting charted data is open for review.
>
> This functionality has been designed to minimise the risk of incorrect data being referenced when making patient notes or prescribing courses of action. The ability to have multiple aspects of the record available at the same time ensures that data can be read and entered without the need to copy, memorise or continually switch screens. With these points in mind we have designed this function to only work within the same record and not to

allow that ability to have elements of different records open at the same time. This could present a risk of cross population of data between patient records and is considered unsafe.

The image below shows the use of multiple screens to access different areas of the same patient record. "

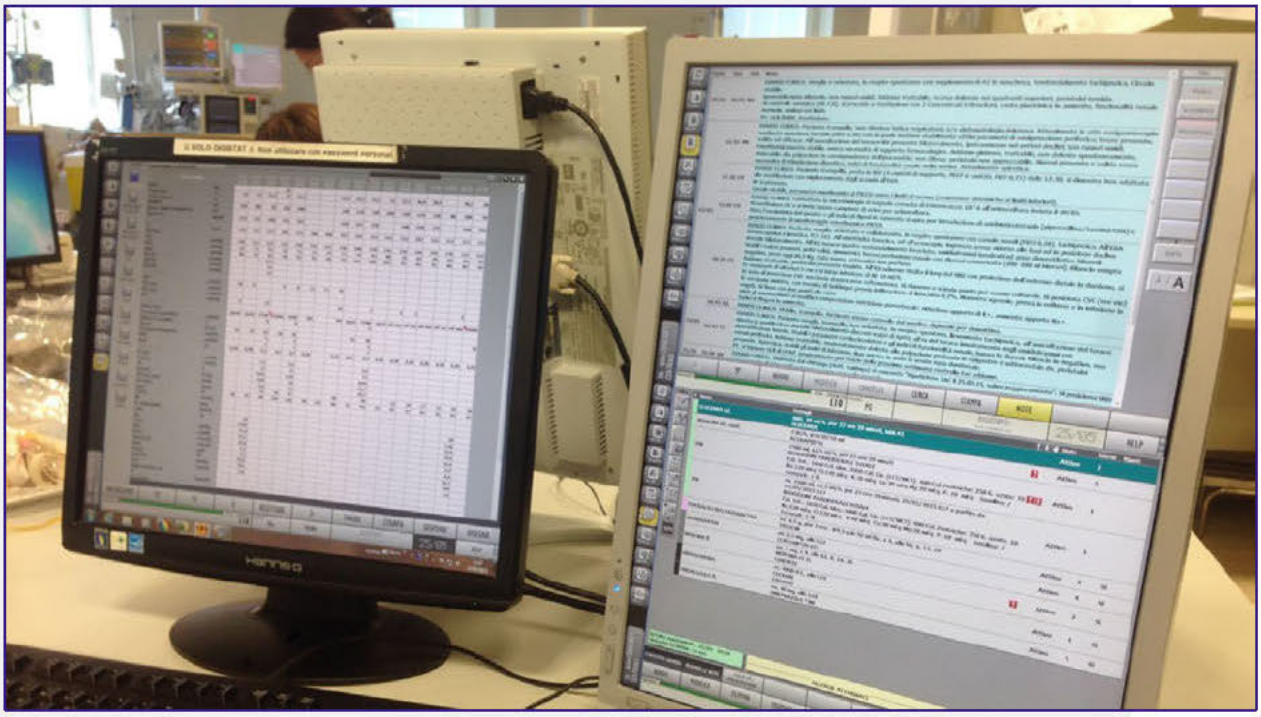


Figure 4: Multiple screen requirement for patient view in WICIS

In WICIS, PDFs are used to present summary views, they pull data from the record and place it alongside the user's task. However, this templated approach often includes irrelevant details and omits necessary information, forcing users to search for relevant historical data. A more effective design would allow for easy navigation through a structured layout with a limited number of tabs, where data entry happens alongside related historical information, such as vital signs.

The current setup encourages the users to rely on information being surfaced via PDF's rather than navigating the record to view information, this poses a risk that clinicians may not have the right information to provide safe care. Proper visualization of trends and a comprehensive view of the patient's status are crucial for informed clinical decision-making.

5.4 Recording & Monitoring Vital Signs

Data from the monitor and other devices are fed to the module called 'online'. The medical device data visualisations are difficult to interpret in real time without applying time filters to identify the correct minute for validation. The ICU workflow is that observations are recorded from the monitor

at hourly intervals (or as determined by the clinician) and then validated by the bedside nurse as part of the ICU workflow. Nursing actions, such as adjusting ventilation or infusions and escalating concerns to the medical team, are based on this review of observations. A benefit of the solution is that these are automatically fed into the patient record for validation, reducing documentation time. A limitation is the graphical views presented in this solution which currently require lots of intervention by the end user to make them readable, these views are crucial for identifying trends and making informed clinical decisions.

5.5 Information Sharing

A key benefit of any EPR is its ability to provide real-time updates and access to patient information from any location, without being limited by physical boundaries. In addition, ICU patients' primary condition will often require them to be under the care of specialist medical and surgical teams for expert input. These teams also need to access and contribute to the patients care record, often remotely. WICIS licencing is per machine, and it was reported that this limits the ability for these staff to view and contribute to the care record. There must be enough licenses to enable this for safety and data governance issues. Given typical Ward based consultant workings, it is rare that a Ward Based Clinician is tied to one ward or a particular PC.

NB: Virtual Machines may be a way round this constraint, allowing access from any PC and tapping into a pool of licenses. This could be explored by DHCW and Ascom for the WICIS Programme. The issue was raised multiple times through different Health Board Interviews and if unresolved could lead to lost benefits of the requirement to access digital systems from anywhere.

5.6 Medicines Management

WICIS includes functionality to prescribe and administer medication through the Ascom therapies module. This effectively makes WICIS an **Electronic Prescribing and Medicines Administration (EPMA)** solution. However, its current design does not meet the standards of specialised EPMA solutions, where both prescribing and administering medicines are supported by presenting clinicians with **safety-critical information** within the workflow, this is known as clinical decision support. Instead, WICIS functions more like a traditional paper drug chart, requiring clinicians to consult external sources such as the **British National Formulary (BNF)** to obtain necessary information for safe prescribing and administration. Unlike the paper record it is not designed with the visual structures and cues that support navigation. This was identified in 2023 when significant work led by a newly appointed WICIS Clinical Lead was undertaken.

5.7 Laboratory Results

The original tendered intention for results was for WICIS to receive a feed of lab results from the Welsh Clinical Portal. It was reported that due to other work pressures of the Lab teams the project had to divert to seeking an alternate solution for results. This resulted in the a workaround where the current WICIS version launches Lab results via an external web browser view of the web

based Welsh Clinical Portal. This loses many benefits and functionality such as results being available directly in the ICU System for interaction with other data, such as ePMA.

The report authors observed via the onsite visit to ABHUB that to launch the context link, WCP, launches in a separate browser window to WICIS, often closing any current WICIS modules or forms, with potential to close down the current clinical document being completed and losing any entered data (as data form entry requires a 'save or save draft' button confirmation). Additionally, the current external contextual window launched for results has the potential to end up with multiple windows open with differing patients as the patient context change in WICIS does not force the subsequent windows to remain in context or close. This is a common problem and hazard with this method of contextual launch into separate uncontrolled windows. It was subsequently reported that this is not the intended designed behaviour and maybe an undesirable feature caused by browser incompatibility. However, the issue has not been investigated since ABHUBs issues log was shared in January 2024.

The programme should review using the split screen function to display Results which would provide WICIS with more technical opportunities to control closing or maintaining patient context. More importantly a direct feed of lab results should be sought to enable full interoperability of results data within the WICIS system such as plotting results against other trends and interactions with the ePMA/Therapies functionality. On review, this external launch of WCP is a local design decision, and an example of where early safety and useability review via appropriate design authority groups should have informed design decisions and Programme Board Escalations should have sought to resolve the core issue of resourcing a full Lab Interface rather than settling for a workaround.

5.8 Nursing Care Plan

This is a task list generated by time bound tasks in the solution. This function is helpful, but it is not a care plan.

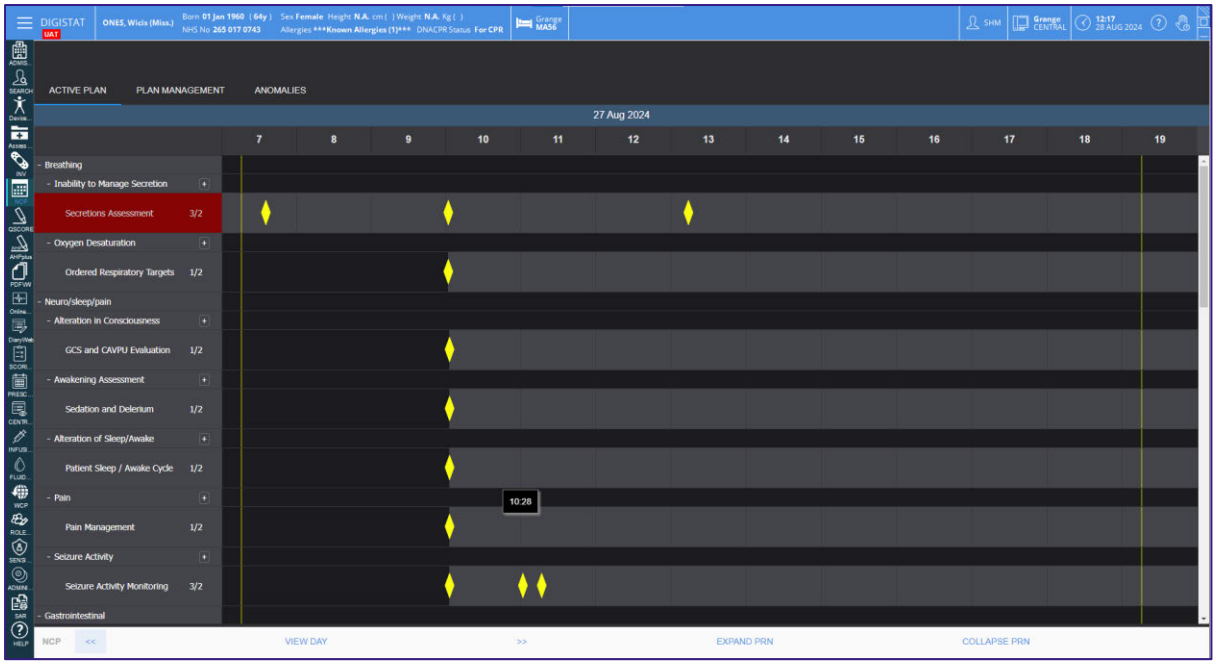


Figure 5: Nursing Care Plan WICIS screenshot

5.9 Overall Clinical Assessment

A review of the solution against clinical workflows revealed multiple issues as documented in the ABUHB log. While individual issues and hazards can usually be mitigated, the sheer volume of them creates a significant usability challenge that creates a hazard of its own; the solution as it is currently configured not only increases the time required to document care but also poses a real risk of failing to attend to and record key elements of patient assessment and care delivery. The extensive changes to current practice required mean that substantial training and education would be necessary, as the solution does not intuitively support common ICU workflows.

6 Contributory Factors/Key Observations

To answer the key questions asked of the independent review pertaining to Clinical Safety of the solution a range of contributory factors have been reviewed. This section provides the key observations, which require a more detailed investigation to generate comprehensive lessons learned for improvement, correcting course.

This section provides observations across the following areas:

- Procurement
- Governance and reporting
- Organisational Change Readiness
- Solution Design & Change Control
- Organisational Change Readiness
    - Stakeholder Analysis & Engagement
    - Technical Readiness

6.1 Procurement

From the Tender specification, supplier response and triangulation with interviews and surveys, it is apparent that the Procurement Specification was not detailed and had not undertaken wide review of Health Boards ICU requirements. However, it was reported during interviews that the requirements and subsequent contract award was approved by the Project Board, including representatives from all Health Boards. The procurement resulted in a very small number of established UK ITU suppliers engaging.

The specification resulted in a very broad brief, with requirements able to be interpreted and met by a range of responses. The terminology used for specification sets all requirements as 'MUST'. This review has not assessed the weighting, prioritisation or scoring methodology of the procurement. However, through a brief analysis of the tender questions and supplier responses it does not appear obvious that any weighting or prioritisation of requirements was set. All requirements are set as 'MUST' statements, typically tender requirements utilise a MoSoCoW method (Must Have, Should Have, Could Have and Will Not Have statements) to assist prioritisation. This gap in prioritisation of requirements may have resulted in all the requirements holding equal value resulting in some critical functionality not appropriately influencing final scores. This could be a contributing factor to the eventual safety concerns which have played out, i.e. less frequently used Subject Access Request (SAR) functionality vs critical and daily used clinical functions (Prescribing, fluid balances and online medical device modules etc.)..

It is noteworthy that the selected supplier openly highlighted that their solution would require redevelopment to meet the tender's requirements for a web-based product, and that this would be complete by the intended Go Live dates stipulated within the tender. It is not clear how the tender weighted this response, and whether the complexities of managing multiple design and development sprints was considered vs a more established and utilised UK solution. A

development programme vs a configuration programme would indicate very different programme methodologies, skill sets, end user engagement and clinical safety efforts required.

Reviewers learned that the ambition for a web-based product were not delivered. While core aspects of the Digistat product is web-based, WICIS is not. It appears that development time was focused on building bespoke functionality for DHCW making a significantly more complex programme as a first of type than adopting a UK tried and tested solution. The need to focus on design rather than configuration may have distracted from other elements of the programme and complicated both supplier and customer clinical safety processes.

The Clinical Safety Standards set by NHS England's DCB0129 and DCB0160 require suppliers to meet specific safety criteria. However, it appears that the recommendations outlined in DCB0160 for applying a Clinical Safety process during procurement were not followed. Documentary evidence shows that the supplier selected had not completed a DCB0129 Safety review at the time of procurement (2018/19). Notably, version 1 of DCB0129 was only created in 2023, and the DHCW DCB0160 was established in November 2023. This suggests that safety and hazard analyses, as well as necessary processes, were not adequately conducted during the design and configuration stages.

The WICIS procurement specification includes a limited (42) number of requirements for ePrescribing and Medicines Administration (ePMA). The UK Department of Health and Social Care's Independent arms-length 'Health Services Safety Investigation Body' (HSSIB) associate ePMA's with both benefits and unintended consequences has led to various toolkits including requirements specifications being developed to aid in procurement and implementation. These toolkits offer detailed procurement requirements, scoring sheets, testing guides, go-live readiness questionnaires, and guidance on standalone versus enterprise EMR. All of which crucial for a comprehensive digital ICU system supporting all aspects of care, including medication management. However it does not appear these freely available guides and toolkits have been adopted as part of the WICIS programme.

6.1.1 Key Procurement Findings

1) Weak requirements and ITT
2) Not using established requirement and toolkits for ePMA

6.2 Governance and Reporting

The roles and responsibilities of differing groups and organisations are not clearly set out from Terms of Reference (ToR) and other governance structures shared. For example, an overarching Governance Structure and reporting lines of the WICIS Programme through the organisations to Executive Board is not available, similarly the structure does not depict the relationships roles & responsibilities between NHS Wales, The NHS Health Collaborative, DHCW, Health Boards and groups such as the National Critical Care Network, further the ToR have not been updated to reflect changes between NHS Wales Health Collaborative and NHS Wales Executive (2023).

The ToR indicates that there was no named Clinical Safety representative in the membership of the inaugural or subsequent Programme Boards, which indicates Safety was not sufficiently prioritised. Reviewers have concluded this as we have not seen evidence of membership and the lateness of commencement of safety activities.

Earlier stages of the programme lacked effective governance to ensure consistent Health Board engagement throughout requirements elicitation and design decisions. This likely led to the late identification of design issues that did not meet local clinical needs, raising risks of "missed care" from system use. The programme should consider, as part of lessons learned, whether there was sufficient check and challenge from the Programme Board to ensure proper design engagement with SMEs and appropriate sign-offs from supporting governance groups. This would allude to questions over whether Senior Programme Board members are sufficiently trained and supported or experienced in what good digital practices and standards are and to know what should be expected, required and established for robust assurance gateways throughout the programme. Something we recommend is explored through a future lesson's learned review as part of a wider reset.

A review of governance documentation, monthly checkpoint reports, and interviews across ABUHB, Ascom, and Health Boards reveals that governance and reporting lack sufficient input from end-user organisations. DHCW checkpoint reports, especially in the risk and issues sections, fail to adequately communicate local project teams' and system users' concerns to the Programme Board sponsors. Highlight reports from December to April did not effectively convey the severity of risks and issues, lacking grading or RAG ratings. This likely led to the underestimation of key hazards by the Board members which had been identified during ABUHB UAT and hazard review. Additionally, the Highlight reports indicate possibly too much reliance on the supplier to review and respond to the ABUHB Hazard log, resulting in delays in escalation, understanding, and appropriate response from Programme sponsors.

A timeline of events from evidence gathered from interviews and documents review shows that:

- DHCW signed off UAT Oct 2023
- ABUHB entered local UAT Nov 2023
- Numerous concerns and escalations raised to DHCW from beginning October 2023 through January 2024 by ABUHB in testing reports, Clinical Director escalations, CNIO escalations & ABUHB Project Board reports
- ABUHB hazard log shared to DHCW Jan 2024
- DHCW highlight report reports ABUHB hazard log passed to Ascom for review Jan 2024
- DHCW checkpoint report April 2024 advises "a requirement to simplify the workflow and system navigation, as well as addressing identified hazards has been identified, resulting in further delay and requirement for additional programme costs."

ABUHB raised concerns through formal programme channels and made repeated requests for assurance, to which they did not receive a response. This ABUH timeline document outlines the programme journey from their perspective and their local project board holds the following risks (WICIS Risk Register Extract.xlsx).

A future lessons learned review should consider:

- Was safety at the core of the Governance of the programme on the agenda?
- Is the CRG the design authority, did all design decisions go through CRG?
- How were Technology Considerations blended with Clinical Processes for overall Design
- At change of NHS Wales Collaborative to NHS Wales Exec, was passing SRO to DHCW (noted in ToR as a supplier) appropriate?
- What is the best collaborative governance to enable success
- Are Programme Boards TOR, members, Quorum and project teams established with sufficiently experienced and qualified SME's to enable success.
- Are external Assurance processes established through major programmes

With regards to lessons learned pertaining to governance, leadership and engagement, it is important to consider areas that worked well as well as those requiring improvement. The authors wish to highlight that throughout their review there was praise, trust, respect and confidence conveyed for the current (delegated) [redacted]. The authors also recognise their openness and keenness to support the review enabling freedom to explore all aspects. Similarly, praise was high across interviews regarding the current supplier Ascom and their management team.

6.3 Organisational Readiness

Digital Transformational Change programmes require organisational and technologic change and readiness activities.

Technological change typically would involve:

- Existing and required technology landscape
- Data
- Systems
- Integration
- Devices (end user devices & medical devices)

Organisational change or people readiness would typically address:

- Leadership and vision
- Staff engagement
- Digital culture
- Digital skills & inclusion
- Attitudes to change
- Benefits management
- Organisational readiness for change
- Ways of working ('As Is' and 'To Be' processes)
- Governance
- Programme management

All these factors contribute to the eventual success and acceptance of the transformation by end users into adopted practices contributing to the safety of the solution and change. It is unclear

whether these were adequately assessed and planned for across Wales ahead of initiation of the WICIS programme.

Through the review, common themes have been identified which may require a lessons learned review to inform any reset.

6.3.1 Technical Readiness

Through interviews and surveys, it is clear that not all Health Boards local infrastructure is 'ready' to enable the digitalisation of ICU. Some themes have arisen pertaining to significant funding required to enable upgrade to core IT Infrastructure (c. £1M required for Cardiff and Vale) and wider reconfiguration of ICU workspaces such as replacing end of bed nurse stations with digital solutions such as 'Computers On Wheels' to enable 'eyes on the patient' whilst recording patient assessments, regular observations validation and care planning.

The technical readiness and wider system integration needs should be assessed as part of any reset, as new systems have been introduced which may require consideration.

6.3.2 People Readiness

Stakeholder maps, role and named individuals analysis do not appear to be of sufficient level to support design and configuration across a complex multi-organisational deployment. The central DHCW stakeholder maps predominantly pertain to Programme Governance between DHCW and supplier whilst the more detailed Engagement Long List within the Communications & Engagement Strategy detail 6 to 7 individuals per Health Board, often [redacted], but do document wider stakeholders and users. The provider Stakeholder Map provides a high-level Programme Governance between DHCW and Ascom but does not map the range of roles at Health Boards who would need further analysis and targeted communications and engagement.

The main principles of the project's Communications and Engagement Strategy are:

- To raise awareness of delivery of the new Welsh Intensive Care Information solution
- To raise awareness of specific functionality to support Intensive Care staff in their work
- To develop understanding and assure Intensive Care staff that this is being developed to suit the needs of the service they deliver
- To build understanding that this will improve the management of patients
- To improve channels of clinical dialogue and standardise documentation across multi-disciplinary teams working in Intensive Care

Without detailed analysis of End User Health Boards as stakeholders the above aims and principles are unlikely to be effectively achieved.

Further the Communications and Engagement Strategy does not cater for a two-way communications loop:

- Are messages sent out by the central programme team being heard?
- What are the receiving organisations, stakeholders (Execs, Project Leads, Clinical and end users) feeding back?
- Are they informed, ready?
- Are End Users ready and accepting of the change?
- Does the solution's design meet End User needs?

This is highly relevant when designing solutions and major change programmes within Health and Care as to the acceptability and safety of the change(s). How widely were the solution designs communicated, and End Users engaged prior to configuration and design decisions being signed off?

As per the observations within the governance section, it has been highlighted as part of this review that there was a lack of consistency in the contribution of SME's through the life of the programme. Furthermore, there was no evidence of defined roles and clear accountabilities for SME's for the full lifecycle of the programme. Table 2 highlights the key roles and responsibilities for SME's:

Role	Responsibility
Define Requirements	Identify and articulate solution needs based on clinical and operational expertise
Guide Design and Configuration	Provide insights to tailor the EHR solution to clinical workflows and departmental needs
Ensure Compliance	Verify that the solution adheres to relevant regulations, standards, and best practices
Train Users	Develop and deliver training to ensure effective use of the EHR solution
Participate in Testing	Engage in UAT to validate solution functionality and identify issues
Manage Risks	Identify and address potential risks and hazards associated with the solution
Support Change Management	Facilitate smooth transitions and address staff concerns during implementation
Promote Continuous Improvement	Provide feedback and suggest enhancements based on user experience
Engage Stakeholders	Collaborate with clinicians, IT teams, and other stakeholders to align the solution with organisational goals
Document and Report	Record findings, decisions, and progress, and report to leadership and stakeholders

Table 3: SME key roles and responsibilities

At the time of solution release to ABUHB, the lack of consistent engagement became evident. Without clear roles for local clinical leadership by SMEs and their confidence in the solution from ongoing involvement, those responsible for leading the rollout could not assure or support their colleagues.

The reviewers conducted a survey across six health boards to glean their experiences of the programme and their confidence and commitment to move forward. Responses were received from all Health Boards and there were fifteen respondents in total with some being combined responses The responses were from Digital Leaders and Clinical Leads (CCIO's, ICU Consultant Leads, CNIOs, ICU Pharmacy Leads, Directors of Digital, ICU Project & Programme Managers).

Results were consistent across all respondents and indicate that Health Board respondents believe engagement through the programme lifecycle was consistently low (Figure 6). The highest score was solution configuration where the average score was three. This tallies with all the other data gathered that shows most activity was in the requirements gathering phase in 2020/21. Many Health Boards cited examples of where they had sought to collaborate with DHCW on local plans but could not get engagement.

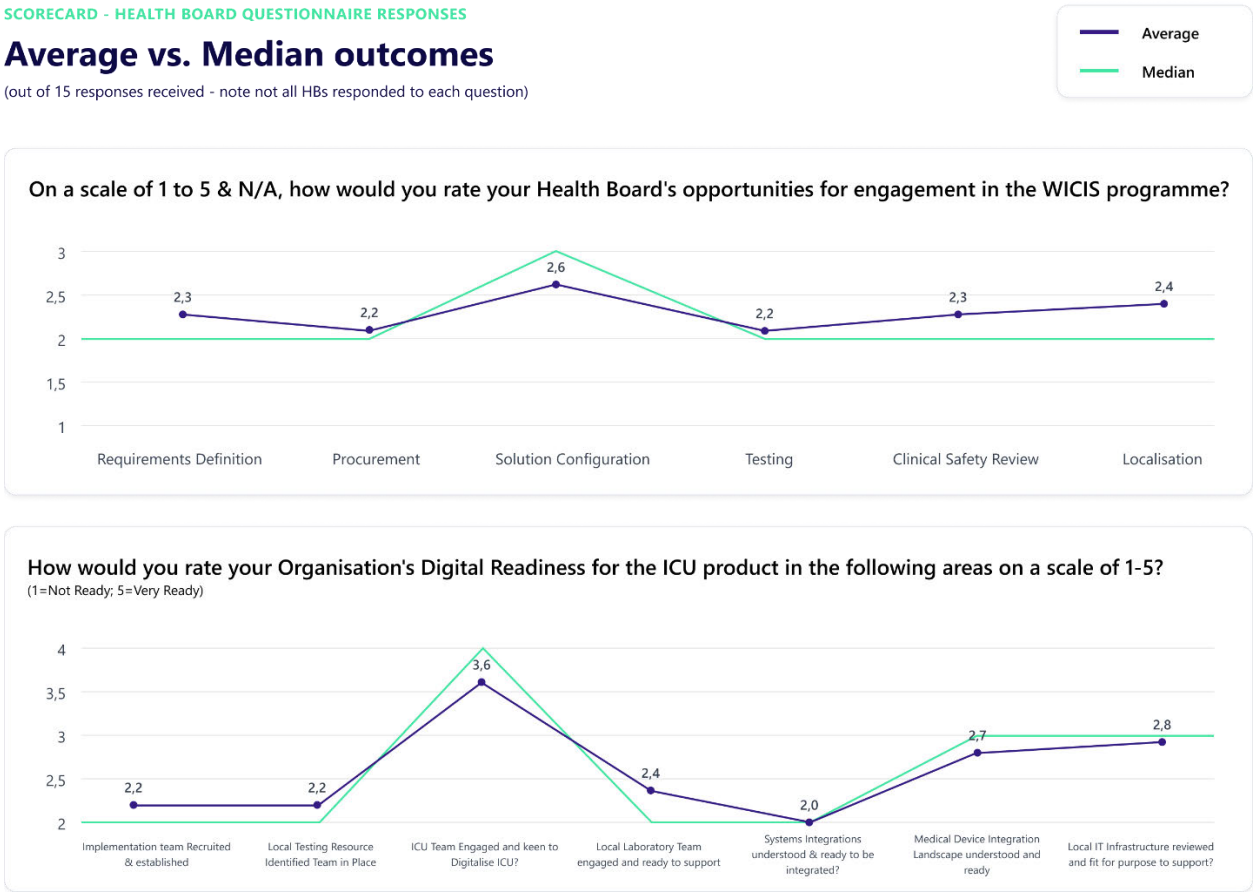


Figure 6: Extract from Health Board Questionnaire responses

"National project engagement with xx was very poor. There was a lack of visibility and poor communication throughout. xx developed a comprehensive project plan at the very outset, but the national programme just did not want to consult on it despite several requests from xx to do so."

Most Health Boards stated they had received little in the way of detail on the simplification process and were unable to comment on its suitability as an alternative that would mitigate their concerns. There has not been a process of bringing together stakeholders, including the supplier, to

collectively review and work through the issues raised at ABUHB to determine their validity, level of risk and mitigation plan since these were raised

Figure 7: WICIS programme chronology

The survey also assessed confidence in the product and the programme, both of which are very low. The results indicate a need to not only focus on product changes but also on programme changes to move forward with success.

Current Confidence in Programme

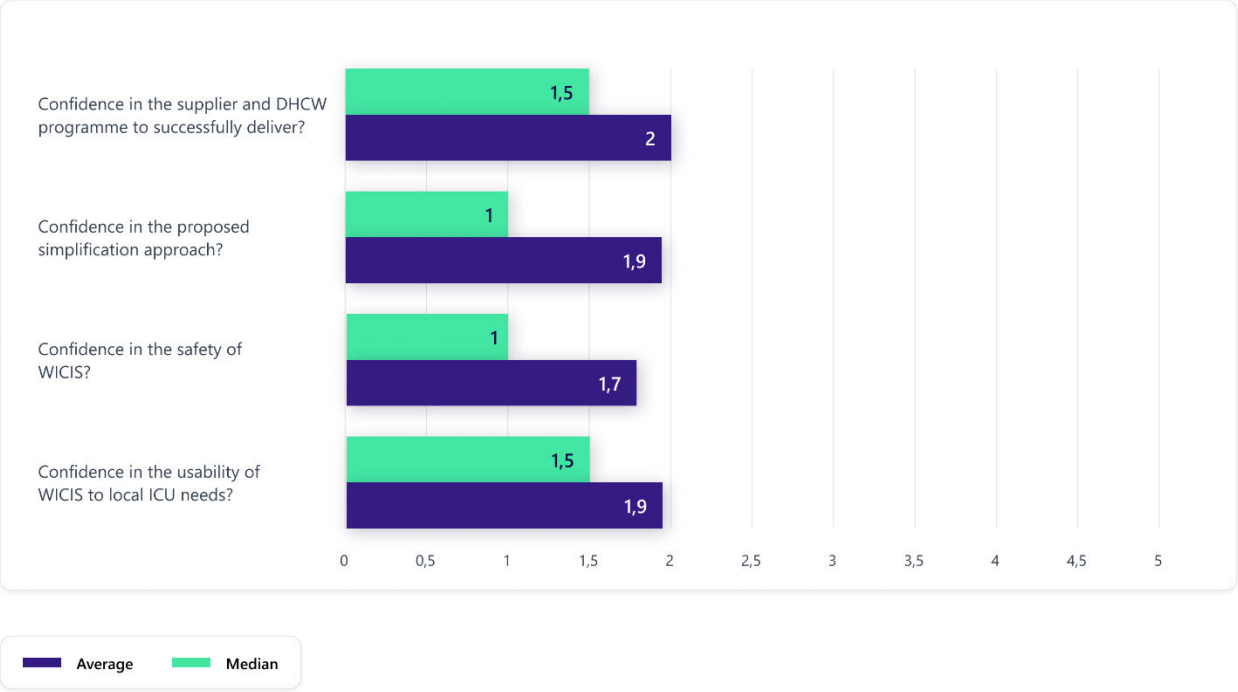


Figure 8: Current confidence in WICIS programme

Across all those surveyed and interviewed in this review, including the supplier, there remains an appetite and sense of urgency to digitise ICU's in Wales. Clinical SME's are particularly concerned that Wales is 'being left behind' and missing opportunities to make care safer and more efficient using digital data. However, our data shows that for those tasked with the wider digital agenda in health boards there are varying priorities in the sequencing of digital programmes. It should be noted however that Welsh Government by including Digitalisation of ICUs in the Digital Priority Investment Fund (DPIF) Programme had prioritised the programme for NHS Wales and Health Boards.

Clinically there is a shared desire to digitise ICU aligned to Welsh Government priorities and this is a useful point of consensus to move forward from.

The quote below is representative of the responses received and indicates the need for more work to be done to reset stakeholder engagement activities.

> "There would have to be a considerable change in the culture for the national programme to be more open and visible. The de facto process of DHCW finding a supplier and then agreeing implementation schedules with very little understanding of HBs capacity and priorities is a process which keeps happening and keeps failing."

6.4 Solution Design & Change Control

Evidence shows that Design Decision workshops were held, but end-user attendance was inconsistent, and roles and responsibilities were unclear. Some system areas had minimal clinical engagement, with only one representative from certain professions. The appropriateness of attendees' skills and knowledge is uncertain, as it is rare for one professional to have expertise across all relevant sub-specialties and documentation needs.

There is no evidence of a feedback loop for workshop participants. Many described submitting paper documents for digitisation. Instead, there appears to have been an overreliance on a small number of expert clinicians at DHCW to interpret workshop outputs and make key design decisions, possibly exacerbated by changes in clinical leadership.

Formal process maps of current and future state workflows were not provided by DHCW, a request has been submitted for "As Is" and "To Be" process maps so that the review can take these into account. Mind Maps have been discussed as being shared to Health Boards through interviews, but these are not depicting end-to-end processes.

ABUHB have produced several current state workflow process maps. This was done at the point of end user acceptance testing when the solution was already built. These maps show how the solution as built does not match clinical workflows.

Through interviews, it became apparent that at times, changes to the solution were made without reference to the end users/health boards or Clinical Reference Group. There is no evidence of a Change Authority Board (CAB), this would typically be managed by an overarching combination of a Technical Design Authority (TDA) and a Clinical Design Authority (CDA) with close engagement with Clinical Safety Technicians and / Officer. Any subsequent lessons learned review and reset should consider the Programme Governance and PMO processes to ensure Change Control processes and documentation are appropriately formed and maintained.

7 Simplification Approach assessment

In response to the submission of ABUHB's hazards and evaluation a proposed simplification was requested and produced by the WICIS clinical lead on 11th March 2024. This was produced in the form of a slide deck with several screen shots and describes a build that is more aligned to ICU workflows than the current set up.

While the Simplification proposal would offer some improvements, it is not comprehensive as it does not address safety critical workflows like medicines prescription and administration. The slides are not of the level of detail required to answer the question "Will it deliver a digital ICU solution that meets the need of end users in Wales ICU care settings" and would require detailed work to be conducted collaboratively across the key stakeholders (End Users, Clinical Champions, Digital Leads and Supplier) to produce a new set of requirements. Key stakeholders at ABUHB and other Health Boards report that they have not seen a simplification proposal and they have not had the opportunity to work through the hazards and issues spreadsheet they submitted with DHCW or Ascom.

The supplier told us that they did not have sufficiently detailed requirements needed to begin any reconfiguration and this was confirmed by the WICIS Clinical Lead.

It was reported to the review that the aim of the simplification proposal was to address the issues raised; to improve workflow and replace the numerous assessments with a typical ICU assessment method of an 'A-E approach', whilst introducing a landing page. It was a swift attempt of commencing a rapid redesign to address key issues. Not a full redesign of the system.

Subsequently the question has been posed, could Wales take the core Digistat product as implemented in Europe, with many citing that what they saw in Bolzano, Italy more closely meets their needs than the end solution produced by the WICIS design. The answer is no, no ICU solution comes straight out of the box without some level of configuration needed and the solution seen was customised for Bolzano. This view was made clear by Ascom (demonstration 2) in a WICIS/Digistat comparison demonstration on 24th April 2024. Figure 9 shows the extent of bespoke build for WICIS that goes beyond simple configuration and indicates the complexity of the solution and points to the fact that simplification is a misnomer in this context. What is proposed in the simplification slides is not merely simplification but significant redesign and reconfiguration.

Figure 9: WICIS bespoke build summary

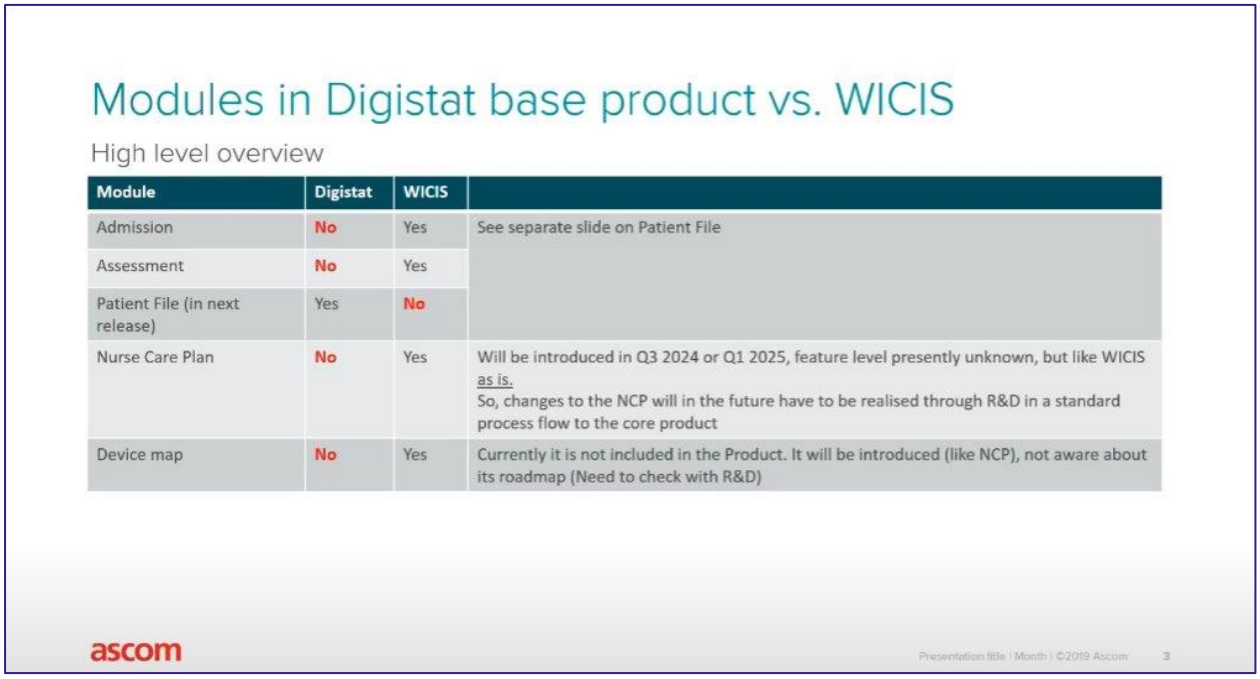


Figure 10: Impact of retrograde move to core Digistat product

Figure 10 summarises the impact of a move back to Digistat core. This slide lists some of the core modules in Digistat and makes a comparison that demonstrates the extent of bespoke WICIS build. This shows that a move back to Digistat core would mean the loss of much of the bespoke build. Some of this bespoke build has moved to R&D at Ascom and so would become available in later releases

This is further shown in figure 11.

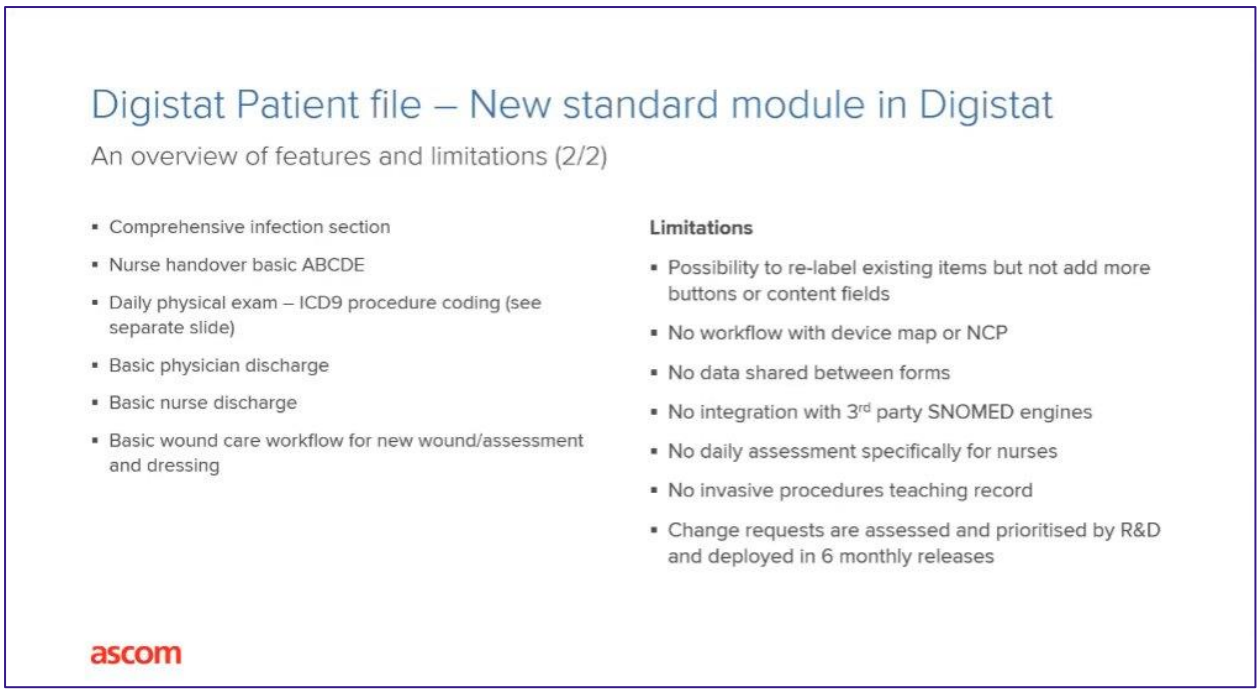


Figure 11: Additional overview of features and limitations on move to core Digistat

All parties concluded that going back to Digistat 'out of the box' was not an option as the build requirements would be too great to match what is currently built in WICIS. Instead, they concluded they would need to continue to develop WICIS to meet end user needs and this could not be achieved on the simplification slides produced by [redacted] but would require a far more detailed requirements gathering exercise. There are no clear outcomes from these demonstrations as all parties stated they needed a management decision to proceed.

An options paper went to NHS Wales Chief Executives seeking further investment with simplification cited as an option. It is unclear how the level of financial investment sought has been arrived at given that simplification requirements were insufficiently defined to enable progression to development and implementation. There has been no further work to further develop a simplification proposal while DHCW await a Welsh Government and NHS Wales decision on options presented.

8 Section 3: Conclusion & Recommendations

This section will examine the three questions posed by NHS Wales in turn and make recommendations for next steps.

8.1 Is the current WICIS solution delivered to ABUHB safe to go live?

For digital transformation to be successful attention must be paid not only to the technology but to processes and people. In assessing whether it is safe to go live with WICIS this review has considered:

People: Wider governance and engagement
Process: The systems and processes for managing clinical safety through the life of the programme
Technology: Ascom's WICIS solution

People – WICIS is essentially an enterprise wide EPR for Welsh Adult ICU services. This means it is more than a technology programme, it is a very complex transformation programme and as such needs strong focus on people readiness and change management. This review found that a very small number of people were engaged in the change and the first time it had any large-scale end user involvement is when it was handed over to ABUHB to implement. This triggered a set of local change management activities that generated an extensive list of clinical hazards, medicolegal and training issues. Ultimately this led to a loss of confidence amongst frontline clinicians and executives at ABUHB and the Health Boards who see themselves as customers of DHCW.

Process – There are several issues associated with the management of clinical safety that led to the very late creation of the extensive log by ABUHB. The evidence reviewed showed that clinical safety activities started very late in the project. DHCW ran what they called modified hazards review through two days of end-to-end user acceptance testing on 24th and 25th July 2023. The lack of clear expectations, roles and responsibilities permeated across the programme and had an impact on decision making across the board.

Technology – The technology has been built to deliver the original vision of a single solution for all ICU care activities across Wales. Many of the design decisions made have ultimately made it cumbersome to work with. Not only does this increase time to document care it also creates risks around data documentation and retrieval that could lead to missed or wrong care and patient harms. These are all captured in a document created by ABUHB that need to be worked through collaboratively with DHCW, Ascom and a cross-health board clinical reference group. This effort would enable a further reassessment of the clinical safety of going live.

The prescribing and administration module is inferior to existing EPMA products on the market as it does not provide any clinical decision support or use the principles of data visualisation that make navigating it easy for the clinician. The benefits it offers are that the integrated nature of all

the modules in WICIS enable some pre population of other parts of the record. The current risk outweighs this benefit

It is the combination of people, process and technology issues that mean it is not currently safe to go live with WICIS.

8.2 Is the proposed simplification proposal viable and safe?

The simplification proposal arose in response to issues raised at ABUHB in January 2024. It was reported that the proposal was produced without wide consultation, in haste and in isolation of other usability and safety activities. It is based on changing the way some data is captured and visualised and does not address all elements of the solution or constitute a comprehensive set of requirements. Using the term simplification is misleading and underestimates the work needed to deliver both the changes laid out in the proposal and to address all the issues raised through local user acceptance testing and hazard identification activities.

As an enterprise-wide solution, the modules in Digistat are interrelated and changes in one part of the solution will affect another requiring careful consideration of 'simplifying' tweaks. A return to the core Digistat solution would not be possible without losing key areas of functionality due to the level of bespoke development for WICIS.

However, findings indicate that this is a highly configurable solution with a flexible supplier who remains committed to delivering WICIS requirements, following a robust exercise in defining the requirements for a reshaped WICIS. Some of these could come from collective collaborative attention to the ABUHB outputs and the DHCW 'simplification' proposal.

It is of note that the suppliers have completed a lessons learned exercise and urge that the programme itself needs to attend to some issues to enable them to successfully complete this reshaping and ultimately implement the product.

In conclusion, further work is needed to capture full requirements, define the best approach and quantify the effort and resources required to deliver WICIS. This requires consideration of the changed digital landscape and strategic context for NHS Wales and its constituent Health Boards.

8.3 Next steps

In conclusion, the reviewers found that this is a programme failure and not necessarily a product failure. We learned that the product is highly configurable, and that it is highly likely that a reshaping of the product could deliver a solution that meets end user needs although the current proposal for this is not of a sufficient standard. Therefore, there is merit in undertaking work to get to a comprehensive revised set of requirements. It is recommended that this work is completed at pace to develop a specification to reshape WICIS.

The large volume of people and process issues surfaced in this review indicate that a full programme reset is also needed to deliver the ambition of the WICIS programme, namely an enterprise-wide electronic patient record for all patients requiring intensive care. This would involve:

- Resetting organisational and individual responsibilities and accountabilities
- Revised governance
- A robust change management approach
- A comprehensive communication and engagement strategy
- Further resources to strengthen the programme delivery team e.g. dedicated roles to cover safety, communication and engagement etc.

The detail required to quantify the cost of the product and programme reset has not been available and therefore it has not been possible to confirm whether the amount requested by DHCW in its options paper would be sufficient to successfully deliver WICIS. Given the amount of work required, the delivery date of March 2025 is highly unlikely. A fully revised programme plan is required based on the quantification of the effort required.

It is important to recognise that the programme commenced in 2019, and the digital and wider health landscape has changed significantly since this time. Therefore, it is recommended that NHS Wales consider its strategic plans for a fully digital Welsh Health system.

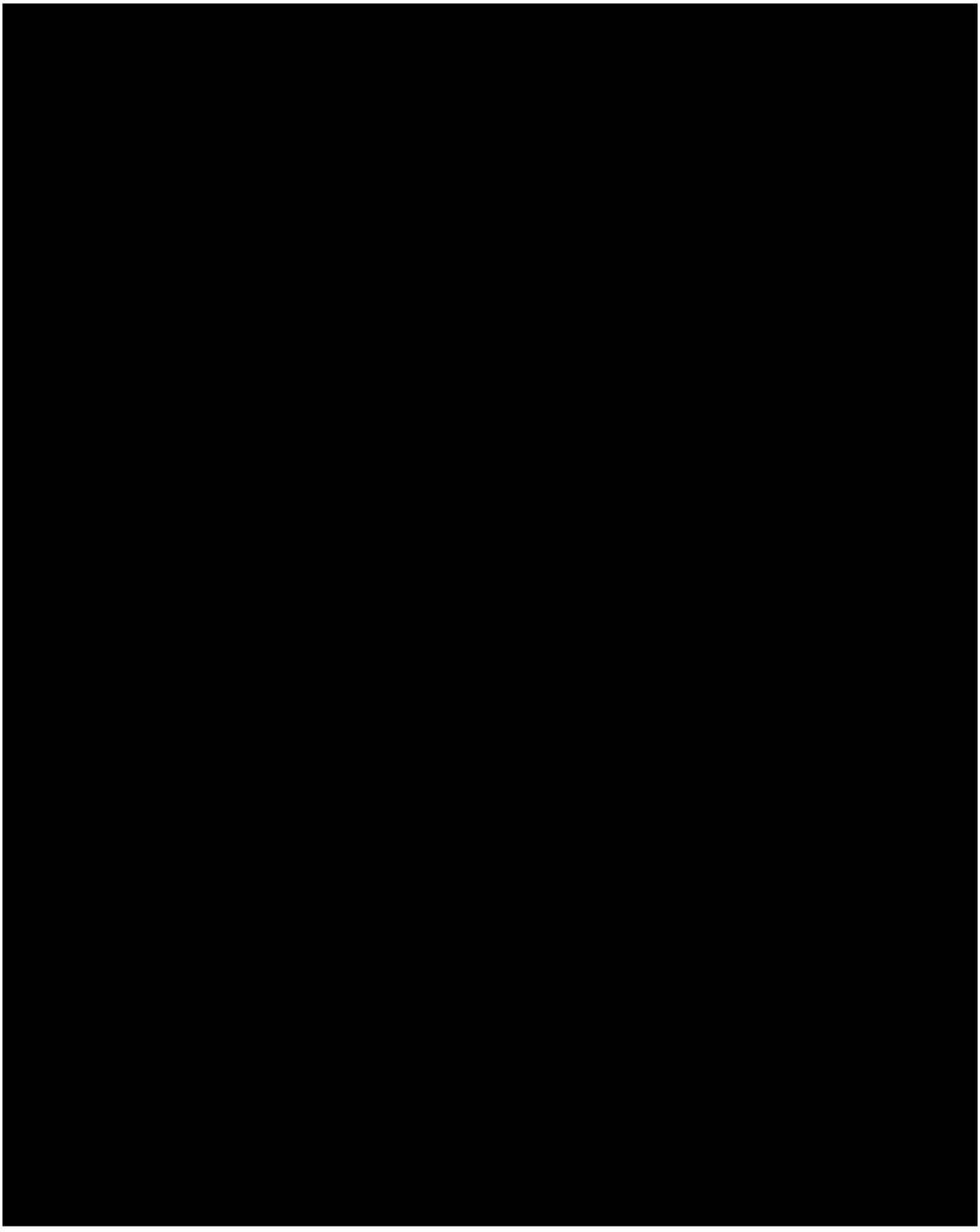
The WICIS programme set off in 2019 with a laudable and ambitious aim:

> The overall aim of the project is to implement a **fully managed electronic solution**, capable of **replacing all paper charts** currently used for recording patient observations on **all Adult Intensive Care Units** across Wales. Providing a common user interface, which will significantly improve the collation and access to clinical information and real time data capture from bedside devices. (DHCW Presentation January 2024)

What this aim doesn't articulate is the why, namely, to make care safer and to improve staff experience. Therefore, this aim remains as pressing now as it was in 2019. Transfers of care are the most dangerous period in patient care and medication errors and omissions of care from a lack of available information are also common safety challenges. Delivering this programme successfully will certainly have a positive impact on patient safety. All of those involved in this review, particularly clinical staff, called out the urgent need for a digital solution and expressed commitment to support this endeavour. The findings of this report provide a basis for a programme reset to achieve this goal.

9 Appendices

Appendix A: STAKEHOLDER ENGAGEMENT



Appendix B: DOCUMENT REFERENCES

Ref	Title	Notes
1.	PRES PDC Feb 2024 WICIS Programme v2	
2.	ABUHB Summary Evaluation of WICIS (2).docx	
3.	Clinical Safety Case Report - Digistat v1.00	
4.	Clinical Safety Case Report - Digistat v1.00 NP Comments	
5.	Hazard Log - Digistat Part one v0.03 Draft WITH COMMENTS	
6.	Hazard Log - Digistat Part Two v0.03 Draft WITH COMMENTS	
7.	Hazard Log - Digistat Part Three v0.03 Draft WITH NOTES	
8.	NP Notes	
9.	Comparison of the Hazard Logs (ABUHB, ASCOM, & DHCW) for the Welsh Intensive Care Information System (WICIS) v2.0	
10.	DHCW Review of ABUHB Clinical Hazard Log	
11.	Hazard log WICIS v1.0 (1).xlsx	
12.	DHCW WICIS UAT Test Report.docx	
13.	SAR Testing.xlsx	
14.	UAT Testing up to 16th Oct.xlsx	
15.	CCCIS Schedule 3 Technical Solution v2.1 as executed.docx	
16.	WICIS Review Recommendations.pptx	
17.	WICIS letter of support from clinicians.docx	
18.	WICISNursing Letter 2024 04 30 (002).docx	
19.	Clinical Leads Meeting on the Future of the WICIS Project.docx	
20.	DHCW-REP- WICIS Escalation 2024 04 25 Updated.docx	
21.	2024 05 14 - DHCW to WG - WICIS Escalations Paper.pdf	
22.	WICIS Architecture - MVP Full d0.2 NS.pdf	
23.	WGO_STK_001_20240718_V1.1_Stakeholder List.xlsx	
24.	CCCIS Instructions to Tenderers v1.0 1.docx	
25.	CCCIS Services Agreement v1.1 amended 29.08.19.docx	
26.	Clinical Safety Case Report - Digistat v1.00.pdf	
27.	WICIS CSC Report v 1.0.docx	
28.	WICIS Highlight Report_Apr 24.pptx	
29.	WICIS Highlight Report_Dec 23.pptx	
30.	WICIS Highlight Report_Feb 24.pptx	
31.	WICIS Highlight Report_Jan 24.pptx	
32.	WICIS Highlight Report_Jun 24.pptx	
33.	WICIS Highlight Report_Mar 24.pptx	
34.	WICIS Highlight Report_May 24.pptx	
35.	WICIS Testing Strategy (1).docx	
36.	Dietetics current process map.vsdx	
37.	Nursing Current Process Map.vsdx	
38.	Pharmacist Admission.vsdx	
39.	Pharmacist Discharge Process.vsdx	

40.	Prescription test script.xlsx	
41.	Script - New admission with issues.xlsx	
42.	Script Template - Nursing Handover.xlsx	
43.	Script Template - ABCDE assessment.xlsx	
44.	Script Template -Nurse discharge.xlsx	
45.	Time and Motion Studies.docx	
46.	SUS results.docx	
47.	WICIS 7. Clerk in new patient with pneumonia scenario.docx	
48.	WICIS 7a. Clerk in new patient with pneumonia - junior doctor.xlsx	
49.	WICIS 7b. Clerk in new patient with pneumonia - consultant.xlsx	
50.	WICIS 12. Review obs trend.docx	
51.	WICIS 12. UAT Script Medics Review Obs Trend.xlsx	
52.	ABUHB Clinical Hazard Log for DHCW final.xlsx	
53.	ABUHB Summary Evaluation of WICIS.DOCX	
54.	WICIS ABUHB Project Assurance Matrix .xlsx	
55.	WICIS ABUHB Project Plan Extract Draft.xlsx	
56.	WICIS Risk Register Extract.xlsx	
57.	WICIS Timeline of Events & Issues.docx	
58.	Clinical Safety Case Report - Digistat v1.10.pdf	
59.	Hazard Log - Digistat v1.10 (NHS D format).xlsx	
60.	Hazard Log - Digistat v1.10.pdf	
61.	Hazard Log - Digistat v1.20 (NHS D format).xlsx	
62.	Hazard log - Digistat v1.20.pdf	
63.	WICIS solution compared with Core Digistat product R 9.x-20240424_150432-Meeting Recording.mp4	
64.	Digistat Demo-20240131_140123-Meeting Recording (1).mp4	
65.	Secondary_Care_Electronic_Prescribing_Implementation_Guidance_5_0.pdf	
66.	Module List reshape shared wit.xlsx	
67.	Lessons Learned Workshop Presentation Version.pptx	
68.	Answer to SmartCos questions v 1.0.odt	
69.	Declaration for WIAG signed.pdf	
70.	WICIS Review.docx	
71.	UMS Digistat Controlbar USR.pdf	

72.	UMS Digistat Diary USR.pdf	
73.	UMS Digistat FluidBalance USR.pdf	
74.	UMS Digistat Forms USR.pdf	
75.	UMS Digistat Infusion USR.pdf	
76.	UMS Digistat Online USR.pdf	
77.	UMS Digistat Product USR.pdf	
78.	UMS Digistat Quick Start Guide.pdf	
79.	UMS Digistat Scoring USR.pdf	
80.	UMS Digistat Therapy USR.pdf	
81.	WIA(2023)_AQP_WICIS_V0-1.docx	
82.	Exercise Scenario book djm.docx	
83.	WICIS Review by SmartCo - Part 1 - Clinical Safety-20240829_102911-Meeting Recording.mp4	
84.	WICIS Review by SmartCo - Part 2 - Simplification of the Workflow-20240830_101013-Meeting Recording.mp4	
85.	WICIS HLR 27.11.2023.docx	
86.	WICIS HLR 29.08.2023.docx	
87.	WICIS HLR 30.10.2023.docx	
88.	WICIS HLR 07.05.2024.docx	
89.	WICIS HLR 22.04.2024.pptx	
90.	WICIS HLR 23.08.2024.docx	
91.	WICIS HLR 25.03.2024.docx	
92.	ABUHB WICIS Response Letter.docx	
93.	ABUHB - WICIS - Delay To Go-Live - Nov 23.docx	
94.	ToR ABUHB WICIS Project Board v1.2.docx	
95.	WICIS ABUHB HLR for Programme Board 19.01.2024.docx	
96.	WICIS ABUHB Training Summary Report.docx	
97.	WICIS HLR 03.10.2023.pptx	

References

- Russ, A. L., et al. (2013). "The effects of cognitive load and task complexity on user performance with EHRs." *Journal of the American Medical Informatics Association*.

- Gardner, R. L., et al. (2018). "Factors associated with clinician burnout and electronic health record use in an academic medical center." *JAMA Network Open*.
- Ratwani, R. M., et al. (2019). "Improving electronic health record usability and safety requires transparency." Journal of Medical Internet Research.

- Friedberg, M. W., et al. (2013). "Factors affecting physician professional satisfaction and their implications for patient care, health systems, and health policy." *Health Affairs*.
- Stevenson, J. E., Nilsson, G. C., Petersson, G. I., and Johansson, P. E. (2010). "Nurses' experience of using electronic patient records in everyday practice in acute/inpatient ward settings: A literature review." BMJ Quality & Safety.

Appendix C: HEALTH BOARD QUESTIONNAIRE

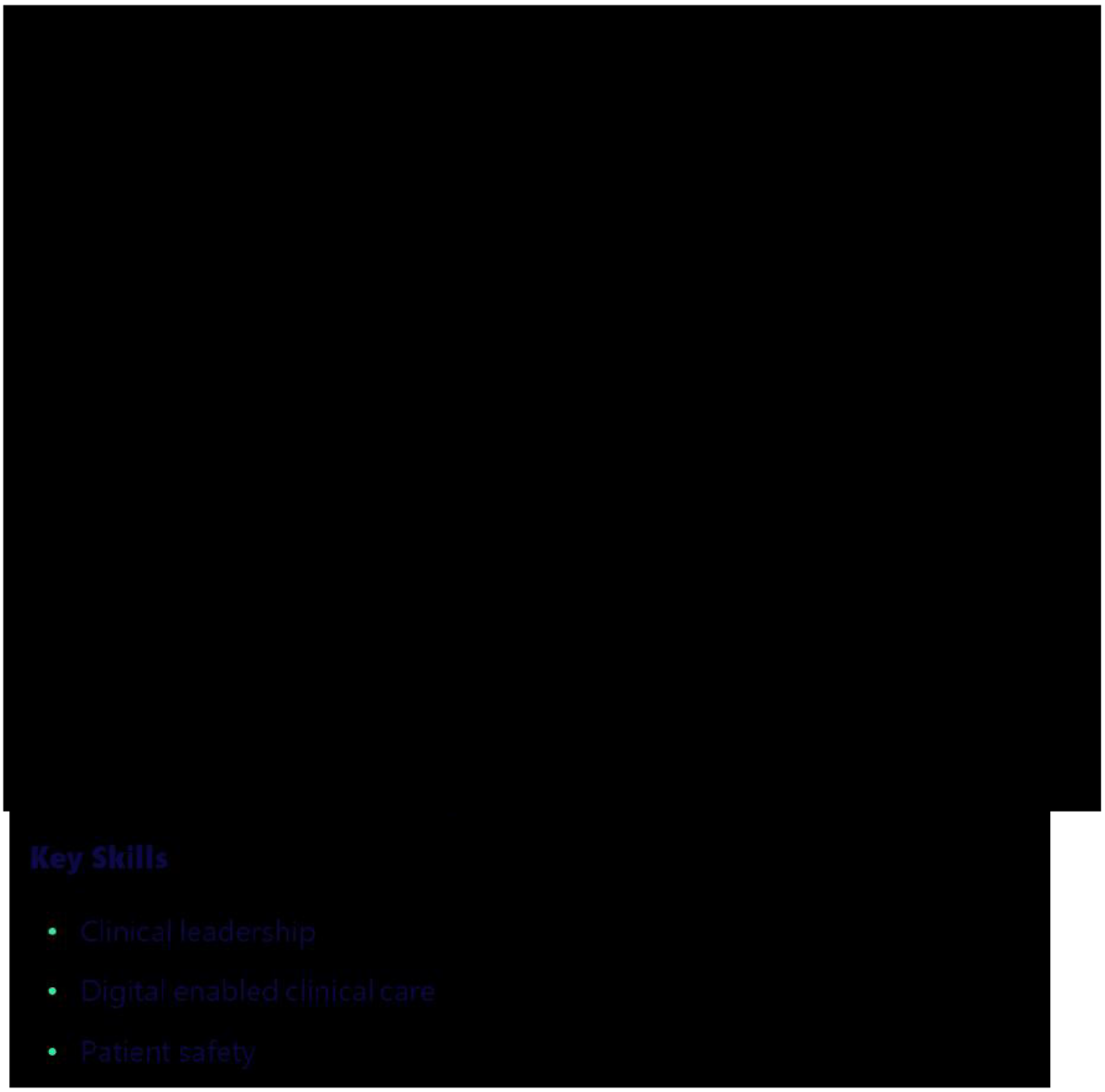
NUMBER	QUESTION
1	Name
2	Role
3	Organisation
4	Describe your involvement in the programme
5	What are your local governance arrangements for the programme, through to overall governance of DHCW and NHS Wales?
6	On a scale of 1 to 5 & N/A, how would you rate your Health Board's opportunities for engagement in the WICIS programme?
6.1	Requirements Definition
6.2	Procurement
6.3	Solution Configuration
6.4	Testing
6.5	Clinical Safety Review
6.6	Localisation
7	Has your Health Board appointed the following roles?
7.1	Project Manager
7.2	Consultant ICU Lead
7.3	Nurse Lead
7.4	Other (if yes please answer Q8)
7.5	Was a Clinical Safety Office directly involved in the programme?
7.6	Was an Clinical Safety Assessment carried out?
8	Other appointed roles
9	Outline your understanding of the key issues and challenges facing the WICIS programme
10	On a scale of 1 to 5 (1 Not Confident 5 = Very confident); How confident are you in the usability of WICIS to your local ICU processes and needs?
11	Please outline areas where you feel less confident
12	On a scale of 1 to 5 (1 = Not Confident 5 = Very confident); How confident are you in the safety of WICIS
13	Please outline your key concerns
14	Have you/your team reviewed the Simplification Proposal?
15	What do you understand about the proposed simplification?
16	On a scale of 1 to 5 (1 = Not Confident 5 = Very confident); how confident are you in the proposed simplification resolving the key issues?

17	How would you rate your Organisation's Digital Readiness for the ICU product in the following areas on a scale of 1 – 5? (1 = Not Ready 5 = Very Ready)
17.1	Implementation team recruited and established
17.2	Local testing resource identified, team in place
17.3	ICU team engaged and keen to digitalise ICU
17.4	Local Laboratory team engaged and ready to support
17.5	System integrations understood and ready to be integrated
17.6	Medical device integration landscape understood and ready Local IT infrastructure reviewed and fit for purpose to support
18	Please describe any concerns with your organisation's readiness for digitalising ICU
19	Do you have a localised deployment Project Plan
20	Where would you place the WICIS implementation in your digital priorities? (On a scale of 1 – 10, with 10 being top priority)
21	What are the top 5 digital priorities for your Health Board?
22	On a scale of 1 to 5 (1 = Not Confident 5 = Very confident); what is your confidence in the supplier and DHCW Programme to successfully deliver this programme?
23	How willing would your Health Board be to invest more public money into the current programme and supplier?
24	Is there anything else you would you like us to know?
25	Would you like to discuss your views on the safety of the WICIS solution in person with SmartCo?

Overview of ABHB onsite visit

1. Overview and demo in a clinical setting of the various workflows with relevant SMEs present
2. Demo of the system in the testing environment which has connected devices and test patients
3. Possibility of including Swansea into the visit – needs to be discussed
4. Overview of the workflows and areas to be discussed:
    - General Overview of the product
    - PAS Admin workflow 'Transfer in / Transfer out'
    - Medical Device integrations (How it was previously with Paper charting, and how it is with the system)
    - Talk through and demo of some key safety issues raised:
    - Labs
    - Meds 'Therapy'
    - Walkthrough of various workflows demonstrated in the care setting if possible:
    - Nursing admission
    - Ward round
    - Medicines administration
    - Sample collection and reporting (end to end workflow)
    - Daily medical round
    - Handover
    - Discharge

Appendix D: TEAM PROFILES

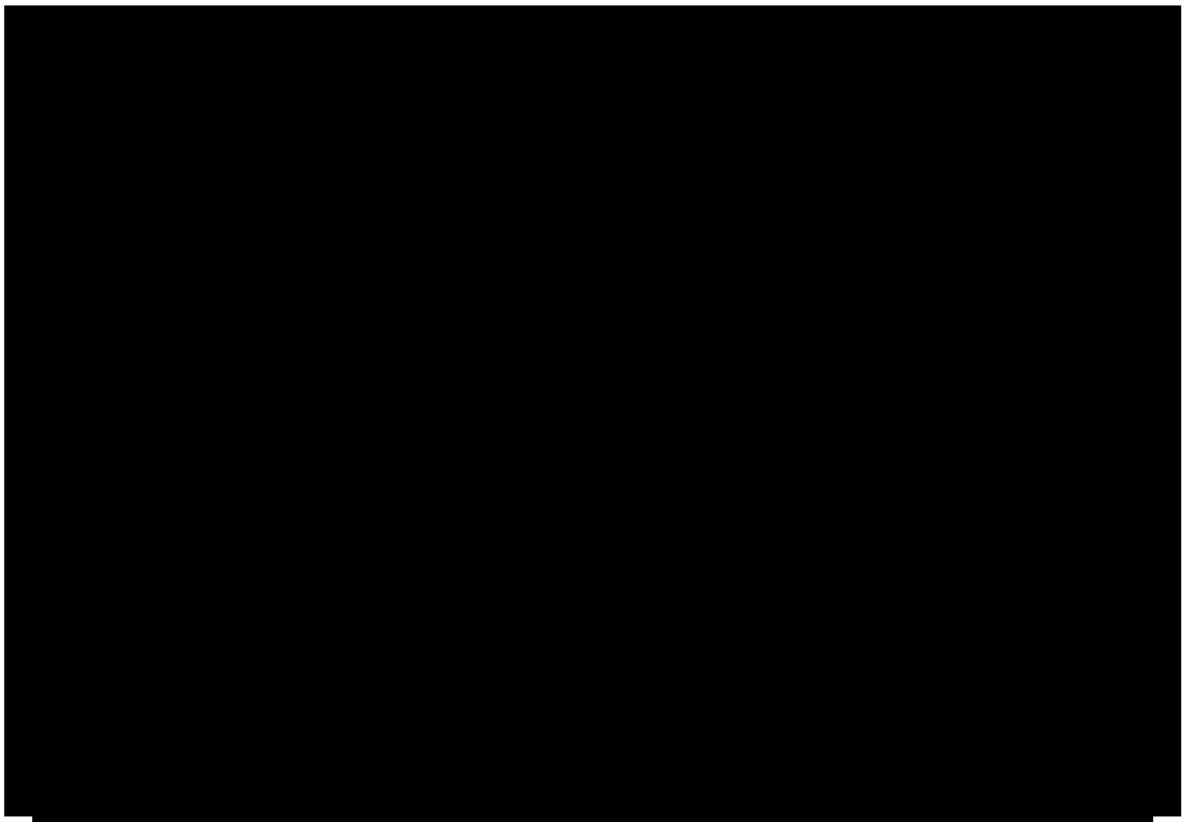


Key Skills

- Clinical leadership
- Digital enabled clinical care
- Patient safety

Key Skills

- Digital transformation
- Digital health innovation
- NHS board level experience



Key Skills

- Programme leadership and assurance
- Digital transformation
- NHS board level experience

Appendix E: REFERENCED DOCUMENTS

Appendix F: TERMS AND DEFINITIONS

Term	Definition
A&E	Accident and Emergency
A – E	Airway, Breathing, Circulation, Disability, Exposure assessment
ABUHB	Aneurin Bevan University Health Board
ADT	Admission, Discharge, Transfer
AHPs	Allied Health Professionals
BNF	British National Formulary
CAB	Change Advisory Board
CDA	Clinical Design Authority
CDIO	Chief Digital Information Officer
CIO	Chief Information Officer
CNIO	Chief Nursing Information Officer
DHCW	Digital Health and Care Wales
ED	Emergency Department (A&E)
ePMA	ePrescribing and Medicines Administration
MoSoCoW	Must Have, Should Have, Could Have and Will Not Have methodology
SAR	Subject Access Request
SBUHB	Swansea Bay University Health Board
SWIFT	So What If This
TDA	Technical Design Authority
UAT	User Acceptance Testing
UKRP	UK Responsible Person